

EXHIBIT 2

Joseph M. Carbone, M.D.

Page 1

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

-----)
IN RE: ETHICON, INC., PELVIC)
REPAIR SYSTEM PRODUCTS) Master File No.:
LIABILITY LITIGATION) 2:12-MD-02327
-----)
THIS DOCUMENT RELATES TO THE) MDL-2327
FOLLOWING CASES IN WAVE 1 OF)
MDL 200:)
DIANE KROPF)
(Case No. 2:12-cv-01202),)
Judy Williams) JOSEPH R. GOODWIN
(Case No. 2:12-cv-00657),) U.S. DISTRICT JUDGE
Myra Byrd)
(Case No. 2:12-cv-00748),)
)
Angela Coleman)
(Case No. 2:12-cv-01267),)
)
Susan Thamen (Reeves))
(Case No. 2:12-cv-00279),)
)
Donna Zoltowski)
(Case No. 2:12-cv-00811),)
)
Plaintiffs,)
vs.)
)
ETHICON, INC., ET AL.,)
)
Defendants.)
)
-----)

DEPOSITION UPON ORAL EXAMINATION

OF JOSEPH M. CARBONE, M.D.

TVT

Danville, Virginia

Thursday, March 17, 2016, 5:45 p.m.

Reported by: Bobbi J. Case, RPR, CCR

Joseph M. Carbone, M.D.

Page 2	Page 4
<p>1 Appearances:</p> <p>2</p> <p>3 ON BEHALF OF THE PLAINTIFFS:</p> <p>4 WAGSTAFF & CARTMELL, LLP</p> <p>5 4740 Grand Avenue, Suite 300</p> <p>6 Kansas City, MO 64112</p> <p>7 (816) 701-1100</p> <p>8 By: NATE JONES, ESQUIRE</p> <p>9 njones@wcllp.com</p> <p>10 ANDREW N. FAES, ESQUIRE</p> <p>11 afaes@wcllp.com</p> <p>12</p> <p>13 ON BEHALF OF THE DEFENDANTS:</p> <p>14</p> <p>15 BUTLER SNOW, LLP</p> <p>16 Renaissance At Colony Park, Suite 1400</p> <p>17 1020 Highland Colony Parkway</p> <p>18 P.O. Box 6010</p> <p>19 Ridgeland, MS 39157</p> <p>20 (601) 985-4596</p> <p>21 By: PAUL S. ROSENBLATT, ESQUIRE</p> <p>22 paul.rosenblatt@butlersnow.com</p> <p>23</p> <p>24</p>	<p>1</p> <p>2 EXHIBITS</p> <p>3 NO. DESCRIPTION PAGE</p> <p>4 1-8 Marked at an earlier deposition ---</p> <p>5 9 Consulting Agreement, Joseph M. Carbone, 72</p> <p>6 M.D., June 10, 2002,</p> <p>7 ETH.MESH.03605451-03605456</p> <p>8 10 Consulting Agreement, Joseph M. Carbone, 78</p> <p>9 M.D., December 22, 2003,</p> <p>10 ETH.MESH.16260588-16260593</p> <p>11 11 Consulting Agreement, Joseph M. Carbone, 79</p> <p>12 M.D., January 5, 2006,</p> <p>13 ETH.MESH.00944191-00944198</p> <p>14 12 Consulting Agreement, Joseph M. Carbone, 82</p> <p>15 M.D., January 11, 2011,</p> <p>16 ETH.MESH.05791448-05791457</p> <p>17 13 Various e-mails, Re: Outstanding 86</p> <p>18 Payments, EH.MESH.19258345-19258347</p> <p>19</p> <p>20 14 July Highlights, YTD of Professional 93</p> <p>21 Education Events,</p> <p>22 ETH.MESH.05794991-05794992</p> <p>23</p> <p>24 15 Various e-mails, Re: GYNECARE Prof. Ed - 101</p> <p>Teaching Engagement Confirmation,</p> <p>ETH.MESH.11842773 & 11842774</p> <p>16</p> <p>17 16 American Urological Association Annual 103</p> <p>18 Meeting Advertising Card,</p> <p>19 ETH.MESH.05793768 & 05793769</p> <p>20</p> <p>21 17 Operation Abbrevio Combat Training Splash 104</p> <p>22 Storyboard, ETH.MESH.09170211-09170213</p> <p>23 18A Three banker boxes of binders 158</p> <p>24 18B</p> <p>18C</p>
Page 3	Page 5
<p>1 INDEX</p> <p>2 DEPONENT EXAMINATION PAGE</p> <p>3 Joseph M. Carbone, M.D. By Mr. Jones 5</p> <p>4 By Mr. Rosenblatt 109</p> <p>5 By Mr. Jones 132</p> <p>6 By Mr. Faes 148</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p>1 Deposition upon oral examination of</p> <p>2 JOSEPH M. CARBONE, M.D., taken on behalf of the</p> <p>3 Plaintiffs, before Bobbi J. Case, Registered</p> <p>4 Professional Reporter and Notary Public for the</p> <p>5 Commonwealth of Virginia at Large, pursuant to notice,</p> <p>6 commencing at 5:45 on March 17, 2016, at the Holiday</p> <p>7 Inn Express, 2121 Riverside Drive, Danville, Virginia;</p> <p>8 and this in accordance with the Federal Rules of Civil</p> <p>9 Procedure.</p> <p>10</p> <p>11 JOSEPH M. CARBONE, M.D., having previously been</p> <p>12 sworn, continued his testimony as follows:</p> <p>13</p> <p>14 EXAMINATION</p> <p>15 BY MR. JONES:</p> <p>16 Q. All right. Doctor, we're back on the record.</p> <p>17 Are you ready to proceed?</p> <p>18 A. Yes, sir.</p> <p>19 Q. Some questions I should have asked you the</p> <p>20 other day that I did not.</p> <p>21 Did you meet with attorneys for Ethicon prior</p> <p>22 to yesterday's deposition?</p> <p>23 A. No, I did not.</p> <p>24 Q. You didn't spend any time preparing with</p>

2 (Pages 2 to 5)

Joseph M. Carbone, M.D.

Page 6	Page 8
<p>1 Ethicon attorneys prior to yesterday's deposition?</p> <p>2 A. Is Matt Moriarty an Ethicon attorney?</p> <p>3 Q. Yes.</p> <p>4 A. Yes, I did.</p> <p>5 Q. Okay. So you met with Ethicon -- you meet</p> <p>6 with an Ethicon attorney prior to your deposition</p> <p>7 yesterday?</p> <p>8 A. Yes.</p> <p>9 Q. His name is Matt Moriarty. Correct?</p> <p>10 A. Yes, I did.</p> <p>11 Q. And he works for the Butler Snow law firm,</p> <p>12 which represents Ethicon. Correct?</p> <p>13 A. Yes.</p> <p>14 Q. Okay.</p> <p>15 MR. ROSENBLATT: Object. I'll represent he's</p> <p>16 with Tucker Ellis, not Butler Snow.</p> <p>17 MR. JONES: Oh, Tucker Ellis.</p> <p>18 THE DEPONENT: Oh, I'm sorry.</p> <p>19 BY MR. JONES:</p> <p>20 Q. So we've established that he works for Tucker</p> <p>21 Ellis.</p> <p>22 He represents, though, Ethicon. Correct?</p> <p>23 A. I guess so, yes.</p> <p>24 Q. Okay. And how long did you meet with</p>	<p>1 met with two different attorneys on multiple occasions.</p> <p>2 Correct?</p> <p>3 A. Yes.</p> <p>4 Q. I take it you felt that you were adequately</p> <p>5 prepared prior to your deposition yesterday?</p> <p>6 A. Yes.</p> <p>7 Q. You did everything you needed to do to</p> <p>8 prepare yourself to answer questions in yesterday's</p> <p>9 deposition?</p> <p>10 A. Everything within my powers as a physician in</p> <p>11 a legal environment.</p> <p>12 Q. You knew ahead of time you were going to be</p> <p>13 asked questions at a deposition about your opinions --</p> <p>14 A. Yes.</p> <p>15 Q. -- in this case?</p> <p>16 A. Yes.</p> <p>17 Q. And you took time to meet with multiple</p> <p>18 attorneys on multiple occasions to prepare yourself.</p> <p>19 Correct?</p> <p>20 A. Yes.</p> <p>21 Q. Okay. Did you meet with any Ethicon</p> <p>22 attorneys today?</p> <p>23 A. Yes.</p> <p>24 Q. Who did you meet with?</p>
Page 7	Page 9
<p>1 Mr. Moriarty?</p> <p>2 A. Well, we started at 5:00, and I met him at</p> <p>3 about 1:00 --</p> <p>4 Q. Okay.</p> <p>5 A. -- and that was on -- yesterday -- no, I</p> <p>6 finished with him at about 3:00. So that was two hours</p> <p>7 yesterday. And then I met with him after work on</p> <p>8 Tuesday from 5:00 to about 10:00.</p> <p>9 Q. Okay. So you met with him on two -- you met</p> <p>10 with Mr. Moriarty on two separate occasions. Correct?</p> <p>11 A. Tuesday and Wednesday.</p> <p>12 Q. Did you meet with any other attorneys for</p> <p>13 Ethicon, other than Mr. Moriarty?</p> <p>14 A. I met with Paul.</p> <p>15 Q. How many times did you met with Paul --</p> <p>16 Mr. Paul Rosenblatt from the firm of Butler Snow prior</p> <p>17 to your deposition?</p> <p>18 A. Prior to yesterday's deposition?</p> <p>19 I met with him yesterday, from about --</p> <p>20 THE DEPONENT: What time did you arrive,</p> <p>21 about 2:00?</p> <p>22 Probably for about an hour.</p> <p>23 BY MR. JONES:</p> <p>24 Q. Okay. Prior to your deposition yesterday you</p>	<p>1 A. Mr. Paul Rosenblatt.</p> <p>2 Q. Okay. How long did you and Paul talk today?</p> <p>3 A. Three hours.</p> <p>4 Q. So you met with Ethicon attorneys again</p> <p>5 today. Correct?</p> <p>6 A. Yes.</p> <p>7 Q. I take it you discussed roughly -- I don't</p> <p>8 want to know what exactly you talked about, but I take</p> <p>9 it when you met with the Ethicon attorney today, you</p> <p>10 talked about the nature of your opinions in this case.</p> <p>11 Correct?</p> <p>12 MR. ROSENBLATT: Object to form.</p> <p>13 Are you talking about all seven cases in</p> <p>14 which he's offering opinions?</p> <p>15 MR. JONES: Everything, yes.</p> <p>16 BY MR. JONES:</p> <p>17 Q. You talked about mesh litigation today with</p> <p>18 Mr. Rosenblatt, didn't you?</p> <p>19 A. Mesh litigation was covered, yes.</p> <p>20 Q. Okay. You talked about your opinions that</p> <p>21 you're rendering in these cases with Mr. Rosenblatt</p> <p>22 today, didn't you?</p> <p>23 A. I think so, yeah.</p> <p>24 Q. Okay. Yesterday we went through the</p>

3 (Pages 6 to 9)

Joseph M. Carbone, M.D.

Page 10	Page 12
<p>1 different companies you've acted for a consultant with.</p> <p>2 I went back and I looked. Did you act as a consultant</p> <p>3 for a company named AstraZeneca?</p> <p>4 A. Yes, I did.</p> <p>5 Q. How long were you a consultant for that</p> <p>6 company?</p> <p>7 A. I apologize. I don't know the term.</p> <p>8 Q. Is it fair to say, when you were a consultant</p> <p>9 for the company AstraZeneca, you were paid by</p> <p>10 AstraZeneca?</p> <p>11 A. Yes.</p> <p>12 Q. Do you recall how much money AstraZeneca paid</p> <p>13 you in your role as a consultant for AstraZeneca?</p> <p>14 A. No, I don't.</p> <p>15 Q. Is that information that you could readily</p> <p>16 obtain for us?</p> <p>17 MR. ROSENBLATT: Object to form.</p> <p>18 Nate, are you going to get into TVT-O at all?</p> <p>19 MR. JONES: Yeah. Yeah. I already did,</p> <p>20 actually, Paul, but thanks.</p> <p>21 THE DEPONENT: No. That's okay.</p> <p>22 The answer is: Not readily, but I can.</p> <p>23 BY MR. JONES:</p> <p>24 Q. But you can get that?</p>	<p>1 provide information to your patients that you're acting</p> <p>2 as a litigation consultant for Ethicon?</p> <p>3 MR. ROSENBLATT: Object to form.</p> <p>4 THE DEPONENT: What -- I guess you'd have to</p> <p>5 define for me what you mean by --</p> <p>6 What kind of information are you talking</p> <p>7 about?</p> <p>8 BY MR. JONES:</p> <p>9 Q. I just told you. Whether you're -- it's</p> <p>10 simple.</p> <p>11 Are you a litigation expert for Ethicon, yes</p> <p>12 or no?</p> <p>13 A. Yes.</p> <p>14 Q. Do you tell patients that?</p> <p>15 A. No.</p> <p>16 Q. Is it reasonable for you to tell patients</p> <p>17 that information?</p> <p>18 MR. ROSENBLATT: Are you asking about his</p> <p>19 male patients or --</p> <p>20 MR. JONES: No. Just answer the question.</p> <p>21 THE DEPONENT: No.</p> <p>22 BY MR. JONES:</p> <p>23 Q. It's not reasonable for you to tell patients</p> <p>24 that information?</p>
Page 11	Page 13
<p>1 A. Yeah. I probably can find out.</p> <p>2 Q. Probably just ask your accountant. Right?</p> <p>3 A. Oh, I'm sorry. I was thinking about asking</p> <p>4 AstraZeneca.</p> <p>5 Q. Oh.</p> <p>6 A. I can ask my accountant. Yeah, and I</p> <p>7 apologize.</p> <p>8 Q. Sure. That's okay.</p> <p>9 Do you think that your work over the course</p> <p>10 of ten years for Ethicon presents any conflict of</p> <p>11 interest whatsoever for you?</p> <p>12 A. No.</p> <p>13 Q. Do you think your work for Ethicon over the</p> <p>14 course of ten years presents any issues of bias for</p> <p>15 you?</p> <p>16 A. No.</p> <p>17 Q. Do you think it's -- do you think it's</p> <p>18 reasonable for you to disclose to your patients that</p> <p>19 you're acting as a litigation consultant for Ethicon</p> <p>20 currently?</p> <p>21 MR. ROSENBLATT: Object to form.</p> <p>22 THE DEPONENT: Restate your question.</p> <p>23 BY MR. JONES:</p> <p>24 Q. Do you think it's reasonable for you to</p>	<p>1 A. No.</p> <p>2 Q. Okay. Do you know that the TVT mesh is</p> <p>3 referred to by Ethicon as old construction hernia mesh?</p> <p>4 A. No, I don't know that.</p> <p>5 Q. You didn't know that before you came here</p> <p>6 today?</p> <p>7 A. I didn't know that the -- Ethicon referred to</p> <p>8 it as old hernia mesh, no.</p> <p>9 Q. Have you ever called the mesh used in TVT old</p> <p>10 construction hernia mesh?</p> <p>11 A. No.</p> <p>12 Q. Have you ever heard that term used before</p> <p>13 today?</p> <p>14 A. No.</p> <p>15 Q. Okay. Have you ever heard the term "old</p> <p>16 construction heavy-weight hernia mesh"?</p> <p>17 A. No.</p> <p>18 Q. Okay. Do you currently perform the Burch</p> <p>19 procedure?</p> <p>20 A. No.</p> <p>21 Q. What surgical procedures do you perform</p> <p>22 related to stress urinary incontinence currently?</p> <p>23 A. I preform the TVT Abbrevio. I perform the TVT</p> <p>24 Exact.</p>

4 (Pages 10 to 13)

Joseph M. Carbone, M.D.

Page 14	Page 16
<p>1 Q. Do you agree there are surgical alternatives</p> <p>2 for the treatment of SUI besides the TVT Abbrevio and</p> <p>3 TVT Exact?</p> <p>4 A. Yes.</p> <p>5 Q. Do you agree there are surgical alternatives</p> <p>6 for the treatment of SUI besides Ethicon TVT mesh?</p> <p>7 A. Yes.</p> <p>8 Q. Do you agree there's surgical alternatives</p> <p>9 for the treatment of SUI besides slings?</p> <p>10 A. Yes.</p> <p>11 Q. Do you agree there are additional treatments</p> <p>12 for SUI besides surgery?</p> <p>13 A. Yes.</p> <p>14 Q. Is it your opinion that the long-term success</p> <p>15 rates between Burch and the TVT are similar?</p> <p>16 A. No.</p> <p>17 Q. What's the difference?</p> <p>18 A. The TVT -- well, the TVT success rate is</p> <p>19 higher.</p> <p>20 Well, again, the question is the long -- you</p> <p>21 mentioned the long-term success. The long-term success</p> <p>22 rate for the TVT is higher.</p> <p>23 Q. Okay. What about the short-term success</p> <p>24 rate, TVT versus Burch?</p>	<p>1 would look at the SGS database comparing the Burch and</p> <p>2 the TVT procedures.</p> <p>3 Q. Okay. And it's your opinion that both the</p> <p>4 Cochrane and SGS database state the long-term success</p> <p>5 rate of TVT is higher than Burch procedure?</p> <p>6 A. The long-term success rate of the TVT is</p> <p>7 higher than the long-term success rate of the Burch</p> <p>8 procedure. That's what I would say.</p> <p>9 Q. According to Cochrane and the SGS database.</p> <p>10 Correct?</p> <p>11 A. Yes.</p> <p>12 Q. Okay. What about long-term complications</p> <p>13 between Burch and TVT, any difference?</p> <p>14 A. Yes, there is a difference.</p> <p>15 Q. Which results in a higher level of complications</p> <p>16 in the long term?</p> <p>17 MR. ROSENBLATT: Object to form.</p> <p>18 THE DEPONENT: Between the Burch and the TVT?</p> <p>19 Again, are you asking specifically the</p> <p>20 TVT Retropubic? Obturator? Abbrevio?</p> <p>21 BY MR. JONES:</p> <p>22 Q. All of those.</p> <p>23 A. All of them combined.</p> <p>24 Q. Like your report.</p>
Page 15	Page 17
<p>1 A. The Burch has a higher short-term success</p> <p>2 rate than it has a longer-term success rate, but I</p> <p>3 still think the TVT has a higher short-term success</p> <p>4 rate.</p> <p>5 Q. Okay. Just so the record's clear, we'll</p> <p>6 break it down.</p> <p>7 TVT head-to-head against Burch, short-term</p> <p>8 success rate, Burch has a higher success rate.</p> <p>9 Correct?</p> <p>10 A. No.</p> <p>11 Q. No?</p> <p>12 A. In short term, the TVT has a higher success</p> <p>13 rate.</p> <p>14 Q. Long term, the TVT has a similar success rate</p> <p>15 as the Burch procedure. Correct?</p> <p>16 A. No. TVT has the higher success rate.</p> <p>17 Q. Will you be offering the opinion in this</p> <p>18 litigation that the short-term and long-term success</p> <p>19 rates of TVT are higher than the Burch procedure?</p> <p>20 A. Yes.</p> <p>21 Q. Is there any -- is there a single study you</p> <p>22 can point -- as you sit here today, that you can point</p> <p>23 to that supports that opinion?</p> <p>24 A. I would look at the Cochrane database. I</p>	<p>1 I'm telling you, it's not in your report.</p> <p>2 A. Okay.</p> <p>3 The TVT has a higher overall complication</p> <p>4 rate. The TVT is similar to that of the Burch</p> <p>5 procedure.</p> <p>6 Q. Okay. The long-term complication rate</p> <p>7 between the TVT line of products and the Burch</p> <p>8 procedure is similar. Correct?</p> <p>9 A. I'd have to defer -- I can't remember the</p> <p>10 specifics, but I'd have to defer to the Cochrane review</p> <p>11 and the SGS.</p> <p>12 Q. As you sit here today, you can't say one way</p> <p>13 or the other TVT complications in the long term are</p> <p>14 similar to Burch complications in the long term.</p> <p>15 Correct?</p> <p>16 MR. ROSENBLATT: Object to form.</p> <p>17 Which complications are you referring to?</p> <p>18 BY MR. JONES:</p> <p>19 Q. Just answer the question.</p> <p>20 A. I haven't memorized the data.</p> <p>21 Q. And that's fine.</p> <p>22 A. Okay.</p> <p>23 Q. You're aware that Ethicon mesh products --</p> <p>24 including Prolift, Prosima, Prolift+M, and TVT</p>

5 (Pages 14 to 17)

Joseph M. Carbone, M.D.

Page 18	Page 20
<p>1 Secure -- are no longer sold by Ethicon. Correct?</p> <p>2 A. List the names again.</p> <p>3 I'm sorry. I just want to make sure --</p> <p>4 Q. You're fine.</p> <p>5 You're aware that Prolift, Prosima, and TVT</p> <p>6 Secure are all Ethicon mesh products no longer sold by</p> <p>7 Ethicon?</p> <p>8 A. Yes.</p> <p>9 Q. You used Prolift, Prosima, and TVT Secure</p> <p>10 Ethicon mesh products. Correct?</p> <p>11 A. Yes.</p> <p>12 Q. You implanted Prolift, Prosima, and TVT</p> <p>13 Secure in women intended to be permanently inside their</p> <p>14 pelvis or vagina. Correct?</p> <p>15 A. Yes.</p> <p>16 Q. You taught other physicians on the use of</p> <p>17 Prolift, Prosima, and TVT Secure. Correct?</p> <p>18 A. Yes.</p> <p>19 Q. Do you ever help Ethicon recruit physicians</p> <p>20 for professional education labs?</p> <p>21 A. No.</p> <p>22 Q. Never?</p> <p>23 A. No.</p> <p>24 Q. You never, over the course of ten years, ever</p>	<p>1 attended a TVT professional education lab?</p> <p>2 MR. ROSENBLATT: Object to form.</p> <p>3 THE DEPONENT: One of the cadaver labs? No.</p> <p>4 BY MR. JONES:</p> <p>5 Q. So what Ethicon paid you to teach other</p> <p>6 physicians how to use an Ethicon mesh product had no</p> <p>7 relationship to the amount of physicians that attended</p> <p>8 that particular lab?</p> <p>9 A. That particular cadaver lab, no.</p> <p>10 Q. You didn't get paid more when more physicians</p> <p>11 attended?</p> <p>12 A. When more physicians attended the cadaver</p> <p>13 lab, no.</p> <p>14 Q. If you did get paid more when more physicians</p> <p>15 attended, would you have any concern with that?</p> <p>16 MR. ROSENBLATT: Object to form.</p> <p>17 THE DEPONENT: I mean, what do you mean by</p> <p>18 "concern"?</p> <p>19 BY MR. JONES:</p> <p>20 Q. Would it bother you as an ethic -- you know,</p> <p>21 in the ethics world at all?</p> <p>22 MR. ROSENBLATT: Object to form.</p> <p>23 Nate, he's here to talk about TVT-O.</p> <p>24 MR. JONES: Yeah, we're talking about it.</p>
Page 19	Page 21
<p>1 helped Ethicon recruit a physician for a professional</p> <p>2 education lab?</p> <p>3 MR. ROSENBLATT: Object to form. Asked and</p> <p>4 answered.</p> <p>5 THE DEPONENT: No.</p> <p>6 BY MR. JONES:</p> <p>7 Q. Do you recall how much you were paid an hour</p> <p>8 to teach other physicians on the use of Prolift,</p> <p>9 Prosima, and TVT Secure?</p> <p>10 MR. ROSENBLATT: I'm going to object. How is</p> <p>11 this --</p> <p>12 MR. JONES: It goes to bias.</p> <p>13 Thanks, Paul. It goes to bias.</p> <p>14 THE DEPONENT: No.</p> <p>15 MR. JONES: Willie asked the same questions</p> <p>16 last week.</p> <p>17 THE DEPONENT: No.</p> <p>18 BY MR. JONES:</p> <p>19 Q. No? Okay.</p> <p>20 A. No, I don't recall per hour.</p> <p>21 Q. Do you recall whether you were paid based on</p> <p>22 how many physicians attended a cadaver lab?</p> <p>23 A. No. I don't think I was.</p> <p>24 Q. Were you paid more or less if more physicians</p>	<p>1 THE DEPONENT: I mean, I didn't, so I never</p> <p>2 really thought about it.</p> <p>3 BY MR. JONES:</p> <p>4 Q. Okay.</p> <p>5 A. I mean, speculating now, I don't see a reason</p> <p>6 for it, but if I could come up with a real reason for</p> <p>7 it, then I could --</p> <p>8 Barring any -- I guess, not having thought</p> <p>9 about it --</p> <p>10 Q. Right.</p> <p>11 A. -- I really can't give -- I mean, if there's</p> <p>12 a real reason, then I could see it. But I don't</p> <p>13 foresee any reason why you should change the revenue at</p> <p>14 a cadaver lab based on the number of physicians you</p> <p>15 train.</p> <p>16 Q. Okay. Are you aware of how much Ethicon, in</p> <p>17 total, paid Dr. Ulf Ulmsten?</p> <p>18 A. No.</p> <p>19 MR. ROSENBLATT: Object to form.</p> <p>20 THE DEPONENT: No.</p> <p>21 BY MR. JONES:</p> <p>22 Q. Are you aware whether it's over \$5 million</p> <p>23 dollars or not?</p> <p>24 MR. ROSENBLATT: Object to form.</p>

6 (Pages 18 to 21)

Joseph M. Carbone, M.D.

Page 22	Page 24
<p>1 THE DEPONENT: If I don't know how much I</p> <p>2 paid him -- they paid him, I don't know if it's over</p> <p>3 5 million.</p> <p>4 BY MR. JONES:</p> <p>5 Q. You don't even know if it's over \$5 or not.</p> <p>6 Right?</p> <p>7 A. I don't know how much they paid him.</p> <p>8 Q. Okay. Do you know if he was a consultant for</p> <p>9 Ethicon at all?</p> <p>10 MR. ROSENBLATT: Object to form.</p> <p>11 THE DEPONENT: I don't know his role, whether</p> <p>12 he was a consultant or what his official role was.</p> <p>13 BY MR. JONES:</p> <p>14 Q. You just know he was the inventor of</p> <p>15 TVT Retropubic though. Correct? Or did you know that?</p> <p>16 A. He invented what later became the</p> <p>17 TVT Retropubic.</p> <p>18 Q. Why do you state it like that, what later</p> <p>19 became --</p> <p>20 A. Because I don't -- I think it became the</p> <p>21 TVT Retropubic when Gynecare bought it.</p> <p>22 Q. Oh.</p> <p>23 A. I mean, he invented the technique when</p> <p>24 Gynecare bought it. My understanding is they labeled</p>	<p>1 What -- what's the nature of these</p> <p>2 complaints? How many complaints?</p> <p>3 A. As best I can recall, two.</p> <p>4 Q. Both in Virginia?</p> <p>5 A. Both in Virginia.</p> <p>6 Q. I'll cut to the chase.</p> <p>7 Do they involve the use of transvaginal mesh</p> <p>8 whatsoever?</p> <p>9 A. No.</p> <p>10 Q. Do they involve the treatment of stress</p> <p>11 urinary incontinence whatsoever?</p> <p>12 A. No.</p> <p>13 Q. Do they involve the treatment of pelvic floor</p> <p>14 disorders whatsoever?</p> <p>15 A. No.</p> <p>16 Q. Okay. Were both complaints dismissed?</p> <p>17 A. Yes.</p> <p>18 Q. Other than that, no disciplinary actions</p> <p>19 whatsoever?</p> <p>20 A. I'm trying to think if I got in trouble for</p> <p>21 not dictating my charts in the hospital, but I don't</p> <p>22 think -- I think I got them all done before they took</p> <p>23 disciplinary action for me.</p> <p>24 Q. Okay. When was this?</p>
Page 23	Page 25
<p>1 it the TVT Retropubic. He invented the technique.</p> <p>2 They called it the TVT Retropubic. That's kind of why</p> <p>3 I say that way.</p> <p>4 Q. I think you're right.</p> <p>5 Did he invent the mesh used in the</p> <p>6 TVT Retropubic?</p> <p>7 A. I know he researched the mesh, but I don't</p> <p>8 know if he invented it.</p> <p>9 MR. ROSENBLATT: Object to scope.</p> <p>10 BY MR. JONES:</p> <p>11 Q. Do you know who Christian Falconer is?</p> <p>12 MR. JONES: By the way, he cites all this</p> <p>13 stuff in his TVT report, Paul, but that's fine. Your</p> <p>14 objection is noted.</p> <p>15 BY MR. JONES:</p> <p>16 Q. Do you know who Christian Falconer is?</p> <p>17 A. No.</p> <p>18 Q. Have you had any disciplinary issues with any</p> <p>19 medical licensing board whatsoever over the course of</p> <p>20 your medical career?</p> <p>21 A. If by that you mean there have been</p> <p>22 complaints that have been investigated and dismissed,</p> <p>23 yes.</p> <p>24 Q. I've got to follow up.</p>	<p>1 A. Years -- years ago.</p> <p>2 Q. In Virginia?</p> <p>3 A. Yeah.</p> <p>4 Q. Nothing in California?</p> <p>5 A. That's so far back.</p> <p>6 Not that I remember.</p> <p>7 Q. Nothing in Missouri?</p> <p>8 A. I believe I was named in a case and later</p> <p>9 dropped as the -- dropped from the suit.</p> <p>10 Q. Okay.</p> <p>11 A. I was deposed, I believe.</p> <p>12 Q. Okay. In the state of Missouri you were</p> <p>13 named in a case and deposed in a matter that involved</p> <p>14 allegations against you as a doctor?</p> <p>15 A. Yes.</p> <p>16 Q. How many times have you been sued?</p> <p>17 A. Other than the one that I cite in California,</p> <p>18 once.</p> <p>19 Q. You just stated California.</p> <p>20 A. Oh, I'm sorry.</p> <p>21 Q. Missouri?</p> <p>22 A. Missouri, yes. I'm sorry. I apologize.</p> <p>23 Q. What was the other suit?</p> <p>24 A. The suit -- I'm sorry.</p>

7 (Pages 22 to 25)

Joseph M. Carbone, M.D.

Page 26	Page 28
<p>1 Q. Did the other suit involve stress urinary 2 incontinence, pelvic floor disorders, or transvaginal 3 mesh at all?</p> <p>4 A. It involved pelvic floor disorders.</p> <p>5 Q. Okay. Tell me more about it then.</p> <p>6 A. It was a rectocele repair that I repaired 7 using a plication technique, a native tissue repair. 8 It was a high rectocele, and during the repair I tacked 9 the bowel to the vagina internally, and it caused a 10 postoperative ileus.</p> <p>11 Q. What was the final resolution of that case?</p> <p>12 A. It was dismissed.</p> <p>13 Q. Okay. Did you feel at all that you made a 14 mistake in your native tissues repair?</p> <p>15 A. Is that an expression of guilt?</p> <p>16 Q. No. No.</p> <p>17 A. I took a high bite --</p> <p>18 Q. Okay. Okay.</p> <p>19 A. -- of tissue, and it was there. I don't want 20 to express guilt.</p> <p>21 Q. That's fine. No. No. That is not an 22 expression of guilt.</p> <p>23 You were asked this yesterday. I've got to 24 ask it again. Have you ever used the Kelly plication</p>	<p>1 Q. Have you ever seen doctors struggle with 2 properly tensioning the TVT mesh in any of your 3 educational labs?</p> <p>4 A. Initially, yes.</p> <p>5 Q. Is there a learning curve with TVT mesh for 6 surgeons?</p> <p>7 MR. ROSENBLATT: Object to form. Vague. 8 Are you asking him about TVT-O?</p> <p>9 BY MR. JONES:</p> <p>10 Q. Just answer the question.</p> <p>11 A. Well, I guess I want you to clarify. Is it 12 use of the mesh or the procedure that uses the mesh?</p> <p>13 Q. Both.</p> <p>14 MR. ROSENBLATT: Object to form.</p> <p>15 THE DEPONENT: Is there a learning curve? 16 Yes.</p> <p>17 BY MR. JONES:</p> <p>18 Q. How many TVT procedures should a doctor 19 perform prior to implanting the TVT mesh inside of 20 women permanently?</p> <p>21 MR. ROSENBLATT: Object to form.</p> <p>22 Nate, are you -- which product are you 23 talking about? 24</p>
Page 27	Page 29
<p>1 technique?</p> <p>2 A. I don't describe it as a Kelly plication. I 3 call it the anterior colporrhaphy. I consider the 4 Kelly plication to go all the way up to the -- as a -- 5 also an anti-incontinence procedure.</p> <p>6 Q. So it's kind of an inconsistent term, 7 semantics --</p> <p>8 A. Right.</p> <p>9 Q. -- but you use --</p> <p>10 A. The anterior colporrhaphy for the treatment 11 of prolapse.</p> <p>12 Q. Do not perform that for SUI, I take it?</p> <p>13 A. No.</p> <p>14 Q. Okay. Do you have any criticisms of the 15 Kelly plication technique for the treatment of SUI 16 whatsoever?</p> <p>17 A. I do not believe it's a very durable 18 procedure.</p> <p>19 Q. Okay. Is the TVT mesh placed tension free 20 underneath the urethra?</p> <p>21 A. The TVT mesh is placed tension free 22 underneath the urethra.</p> <p>23 Q. So that's a yes?</p> <p>24 A. Yes.</p>	<p>1 BY MR. JONES:</p> <p>2 Q. Just answer the question.</p> <p>3 A. Well, I believe there was a study that 4 compared, quote/unquote, high-volume versus low-volume 5 surgeons, and that's the only one I can refer to.</p> <p>6 Q. Got to ask the question. I didn't ask about 7 any studies.</p> <p>8 A. Okay.</p> <p>9 Q. I'm just asking you your opinion, as someone 10 holding themselves out as an expert in transvaginal 11 mesh litigation, specifically on TVT mesh. How many 12 TVT procedures should a doctor perform prior to using 13 that product in a woman, in your opinion?</p> <p>14 MR. ROSENBLATT: Object to form.</p> <p>15 THE DEPONENT: The answer varies, dependent 16 on the experience of the physician with the use of -- 17 with their surgical experience, with the treatment of 18 pelvic -- with the treatment of stress urinary 19 incontinence, with the treatment -- well, with vaginal 20 surgery in general, with treatment of stress urinary 21 incontinence in specific, and even more specific, in 22 the use of vaginal meshes.</p> <p>23 BY MR. JONES:</p> <p>24 Q. Okay. Let me see if I can get an answer to</p>

8 (Pages 26 to 29)

Joseph M. Carbone, M.D.

Page 30	Page 32
<p>1 this question.</p> <p>2 If a physician has never used Ethicon mesh</p> <p>3 products before, never used TVT mesh before, has ten</p> <p>4 years of experience as a urologist but not a</p> <p>5 urogynecologist, is not a consultant for any mesh</p> <p>6 company, how many TVTs does that surgeon need to do</p> <p>7 before they can use it in a patient?</p> <p>8 MR. ROSENBLATT: Object to form.</p> <p>9 THE DEPONENT: Again, you haven't expressed</p> <p>10 all the variables that I can consider in --</p> <p>11 BY MR. JONES:</p> <p>12 Q. It's too complicated. Right?</p> <p>13 A. Too complicated to answer.</p> <p>14 Q. It's too complicated. That is a dumb</p> <p>15 question.</p> <p>16 Have you ever reported a mesh complication to</p> <p>17 Ethicon?</p> <p>18 A. Yes, I have.</p> <p>19 Q. Which ones?</p> <p>20 A. I would have to go to MAUDE Database to</p> <p>21 remember.</p> <p>22 Q. Okay. So these would be ones that you</p> <p>23 reported to the FDA?</p> <p>24 A. Yeah, to the MAUDE Database.</p>	<p>1 A. Can you -- no, because you said something</p> <p>2 there that I didn't say.</p> <p>3 Q. What was that?</p> <p>4 A. All these complications you reported to</p> <p>5 Ethicon.</p> <p>6 Q. Yeah. That was -- erase that from your mind.</p> <p>7 A. No, but you said it.</p> <p>8 Q. I know I said it. It wasn't a question.</p> <p>9 Let's start over. Let's start over.</p> <p>10 A. Do you see what I'm saying?</p> <p>11 Q. I get it.</p> <p>12 A. You're asking me --</p> <p>13 Q. I get it. Let's start over.</p> <p>14 A. -- how many questions I've reported to</p> <p>15 Ethicon.</p> <p>16 Q. Let's start over.</p> <p>17 A. I'm sorry. I apologize. Go ahead.</p> <p>18 Q. I told you I was going to --</p> <p>19 A. Okay. I'm sorry. I apologize.</p> <p>20 Q. -- get confused and ask poor questions.</p> <p>21 A. Okay. Go ahead.</p> <p>22 Q. If we go to the MAUDE Database and we pull</p> <p>23 the complaints you've reported to the FDA --</p> <p>24 A. Yes.</p>
Page 31	Page 33
<p>1 Q. Have you ever reported a mesh complication to</p> <p>2 Ethicon that you didn't report to the FDA?</p> <p>3 A. No.</p> <p>4 Q. So if we go to the MAUDE Database, search</p> <p>5 your name, pull those complaints, that will represent</p> <p>6 every single time you've reported a mesh complication</p> <p>7 to Ethicon. Correct?</p> <p>8 A. Restate your question.</p> <p>9 Q. Yeah.</p> <p>10 If we go to the MAUDE Database --</p> <p>11 A. Right.</p> <p>12 Q. -- to pull the complaints you've reported to</p> <p>13 the FDA, we'll know that represents ever mesh</p> <p>14 complications you've reported to Ethicon. Correct?</p> <p>15 A. You mean in an official capacity? I mean,</p> <p>16 I --</p> <p>17 Q. No. I didn't ask official or --</p> <p>18 I just want to know how we get all these</p> <p>19 complications that you reported to Ethicon, and you</p> <p>20 said every one I reported to the FDA. So I want to</p> <p>21 know, if I go to the FDA and I pull the MAUDE Database</p> <p>22 complaints, will that represent all the times you</p> <p>23 reported a mesh complication to Ethicon, no matter</p> <p>24 official, unofficial.</p>	<p>1 Q. Are you following me?</p> <p>2 A. I'm with you.</p> <p>3 Q. Got it.</p> <p>4 -- that will represent all of the mesh</p> <p>5 complications you reported to Ethicon. Correct?</p> <p>6 MR. ROSENBLATT: Object to form. Vague.</p> <p>7 THE DEPONENT: I'm trying to think if I</p> <p>8 really talk much about my complications to anybody. I</p> <p>9 mean, the one that I reported to the MAUDE database, I</p> <p>10 did.</p> <p>11 And to answer your question, I don't -- I</p> <p>12 don't remember. I really don't.</p> <p>13 BY MR. JONES:</p> <p>14 Q. That's fair.</p> <p>15 A. I apologize.</p> <p>16 Q. An honest answer. I appreciate that.</p> <p>17 It sounds like you reported one mesh</p> <p>18 complications to the MAUDE Database. Correct?</p> <p>19 A. Yes.</p> <p>20 Q. A total of one?</p> <p>21 A. Yes.</p> <p>22 Q. Didn't report more than one mesh complication</p> <p>23 to the MAUDE Database. Correct?</p> <p>24 A. No.</p>

9 (Pages 30 to 33)

Joseph M. Carbone, M.D.

Page 34	Page 36
<p>1 Q. A total of one. Correct?</p> <p>2 A. Yes.</p> <p>3 Q. Okay. And that's over your entire medical</p> <p>4 career, you've reported one mesh complication to the</p> <p>5 MAUDE Database?</p> <p>6 A. Yes.</p> <p>7 Q. And is that a mesh that you implanted?</p> <p>8 A. Yes.</p> <p>9 Q. What product was it?</p> <p>10 A. I believe it was TVT Retropubic.</p> <p>11 Q. What was the mesh complication?</p> <p>12 A. I believe it was one of my first erosions.</p> <p>13 Q. And when was this?</p> <p>14 A. Oh, early on. I would say probably 2000 -- I</p> <p>15 can't remember the exact date.</p> <p>16 Q. Okay.</p> <p>17 A. In the early part of my medical career.</p> <p>18 Q. Early 2000s. Fair?</p> <p>19 A. That's fair to say, yes.</p> <p>20 Q. Since the early 2000s, you have not reported</p> <p>21 a single mesh complication. Correct?</p> <p>22 A. That's not correct.</p> <p>23 Q. Okay. Correct me.</p> <p>24 A. I have not reported a single complication to</p>	<p>1 newsletter?</p> <p>2 A. There's a lot of AUA newsletters.</p> <p>3 Q. Are you familiar with the annual AUA</p> <p>4 newsletter? Do you subscribe to the AUA newsletter?</p> <p>5 A. The AUA newsletter comes out to all AUA</p> <p>6 members.</p> <p>7 Q. Okay.</p> <p>8 A. I don't subscribe to it.</p> <p>9 Q. Okay. You get it because you're a member?</p> <p>10 A. Yes.</p> <p>11 Q. Okay. Can the TVT-O mesh ever be completely</p> <p>12 removed?</p> <p>13 MR. ROSENBLATT: Object to form.</p> <p>14 MR. JONES: I thought you'd like that one,</p> <p>15 Paul.</p> <p>16 MR. ROSENBLATT: Well, now you're talking</p> <p>17 about the product that you have the two hours to talk</p> <p>18 about, so good work.</p> <p>19 MR. JONES: Thank you.</p> <p>20 THE DEPONENT: Can the TVT mesh ever be</p> <p>21 completely removed?</p> <p>22 I'm sorry, the TVT-O. You are limiting it</p> <p>23 now to the TVT-O. Thank you, I was getting confused</p> <p>24 there.</p>
Page 35	Page 37
<p>1 the MAUDE Database.</p> <p>2 Q. Who have you reported it to?</p> <p>3 A. I guess I probably told my wife.</p> <p>4 Q. Okay. Other than your wife, you report it to</p> <p>5 anybody?</p> <p>6 A. I probably told my partner about it.</p> <p>7 Q. Other than your partner and wife?</p> <p>8 A. I don't remember specifically who I discussed</p> <p>9 them with.</p> <p>10 Q. Okay.</p> <p>11 A. I try to keep them -- it's a small town.</p> <p>12 Q. Sure. Sure. I realize that.</p> <p>13 Does the Nilsson Ulmsten 17-year data -- you</p> <p>14 know what I'm talking about when I call it the Nilsson</p> <p>15 Ulmsten 17-year data?</p> <p>16 A. I'm familiar with the article. I'm not going</p> <p>17 to be able to quote you specifics on it.</p> <p>18 Q. But you know -- we're talking about the same</p> <p>19 thing. Right?</p> <p>20 A. I believe so, yes.</p> <p>21 Q. Okay. Does the Nilsson Ulmsten 17-year data</p> <p>22 apply to TVT laser cut mesh?</p> <p>23 A. No.</p> <p>24 Q. Okay. Are you familiar with the AUA</p>	<p>1 Yes.</p> <p>2 BY MR. JONES:</p> <p>3 Q. Yes, it can be.</p> <p>4 A. Yes.</p> <p>5 Q. Have you ever fully removed a TVT-O mesh from</p> <p>6 a patient?</p> <p>7 A. No.</p> <p>8 Q. Have you ever seen a TVT-O mesh fully removed</p> <p>9 from a patient?</p> <p>10 A. No.</p> <p>11 Q. Have you ever read about a TVT-O mesh being</p> <p>12 fully removed from a patient?</p> <p>13 A. I don't recall. I don't think so.</p> <p>14 Q. Okay. As you sit here today, can you point</p> <p>15 me to a single source to support your statement that</p> <p>16 the TVT-O mesh can be fully removed from a patient?</p> <p>17 A. I can't recall one.</p> <p>18 Q. Okay. When did Ethicon first start selling</p> <p>19 laser cut mesh in the TVT products?</p> <p>20 A. Was it 2008 --</p> <p>21 Q. Okay.</p> <p>22 A. -- I believe.</p> <p>23 Q. Okay. I've got some questions about pore</p> <p>24 size and weight. I asked you a little bit about this</p>

10 (Pages 34 to 37)

Joseph M. Carbone, M.D.

Page 38	Page 40
<p>1 yesterday, and I'm going to limit this line of</p> <p>2 questioning to the TVT line of products.</p> <p>3 And just for the record, did you issue a</p> <p>4 TVT-O expert report in this case?</p> <p>5 A. No. I just -- this is the report I provided.</p> <p>6 Q. Okay. Thank you for that.</p> <p>7 MR. ROSENBLATT: And I'll represent that was</p> <p>8 his TVT, TVT-O report. You've asked about TVT --</p> <p>9 MR. JONES: Yeah. I get it.</p> <p>10 BY MR. JONES:</p> <p>11 Q. There's only one report. Right? For TVT and</p> <p>12 TVT-O. Right?</p> <p>13 A. That is it.</p> <p>14 Q. Got it. I'm going to ask you questions about</p> <p>15 that report.</p> <p>16 I'm going to limit questions about pore size</p> <p>17 and density to the TVT line of products. Okay?</p> <p>18 Do larger pores used in mesh for the</p> <p>19 treatment of SUI result in lower inflammation for the</p> <p>20 patient?</p> <p>21 MR. ROSENBLATT: Object to form.</p> <p>22 THE DEPONENT: Repeat it again.</p> <p>23 BY MR. JONES:</p> <p>24 Q. Larger pores used in a mesh for treatment of</p>	<p>1 Q. Let me stop you.</p> <p>2 Is there a difference in the pore size in TVT</p> <p>3 mesh, TVT-S mesh, TVT-O mesh, TVT Abbrevio mesh, or TVT</p> <p>4 Exact mesh?</p> <p>5 A. No.</p> <p>6 Q. So they're all the same pore size?</p> <p>7 A. They're all the same mesh.</p> <p>8 Q. Okay. All the same weight, too. Right?</p> <p>9 A. Yeah.</p> <p>10 Q. Okay.</p> <p>11 A. So I guess that's why I didn't understand</p> <p>12 your question.</p> <p>13 Q. Does making the pores larger in TVT mesh</p> <p>14 result in a lower inflammatory response in the patient?</p> <p>15 MR. ROSENBLATT: Object to form.</p> <p>16 THE DEPONENT: Because if you're limiting it</p> <p>17 to just those products, the question has no meaning</p> <p>18 because there's no difference.</p> <p>19 BY MR. JONES:</p> <p>20 Q. There's no difference in pore size. If you</p> <p>21 increase the TVT mesh, there's no difference in the</p> <p>22 inflammatory response. Correct?</p> <p>23 MR. ROSENBLATT: Object to form.</p> <p>24 THE DEPONENT: The pore size didn't increase</p>
Page 39	Page 41
<p>1 SUI result in lower inflammation for patients?</p> <p>2 MR. ROSENBLATT: Larger than what, Nate?</p> <p>3 BY MR. JONES:</p> <p>4 Q. Just answer the question.</p> <p>5 A. I can't say that specifically.</p> <p>6 Q. Okay. Yes or no, does a lighter-weight mesh</p> <p>7 used for the treatment of SUI result in lower</p> <p>8 inflammation for the patient?</p> <p>9 MR. ROSENBLATT: Object to form.</p> <p>10 THE DEPONENT: Again, I -- you know, the term</p> <p>11 "lighter" -- I mean, I guess I'm asking you to define</p> <p>12 what are you comparing --</p> <p>13 BY MR. JONES:</p> <p>14 Q. TVT.</p> <p>15 Again, all my questions are related to TVT so</p> <p>16 I'm comparing everything to TVT mesh. Okay? My next</p> <p>17 ten questions all compared to TVT mesh. With me?</p> <p>18 A. The different meshes?</p> <p>19 Q. TVT mesh.</p> <p>20 A. TVT Retropubic, TVT-A, TVT-O, TVT-S.</p> <p>21 Q. Right.</p> <p>22 A. So ask --</p> <p>23 Q. Let me stop --</p> <p>24 A. What's your question?</p>	<p>1 between the TVT Retropubic to the TVT Obturator, the</p> <p>2 TVT-S, and the TVT-A. So since there was no increase</p> <p>3 amongst those products, there was no inflammatory</p> <p>4 change difference.</p> <p>5 BY MR. JONES:</p> <p>6 Q. Ethicon never made the pore size larger in</p> <p>7 any of their TVT products. Correct?</p> <p>8 A. In their -- yes, in their TVT products,</p> <p>9 stress urinary incontinence.</p> <p>10 Q. Ethicon never decreased the weight of the</p> <p>11 mesh in any of their TVT products. Correct?</p> <p>12 A. Not that I'm aware of, no.</p> <p>13 Q. Does the foreign body response to the TVT</p> <p>14 mesh ever go away for a woman?</p> <p>15 MR. JONES: Object to form.</p> <p>16 THE DEPONENT: I mean, what do you mean by</p> <p>17 "foreign body response," the transient inflammatory</p> <p>18 response?</p> <p>19 BY MR. JONES:</p> <p>20 Q. How about this? I will make it as simple as</p> <p>21 I can.</p> <p>22 Does the woman's body ever stop reacting to</p> <p>23 the TVT mesh inside her vagina, yes or no?</p> <p>24 MR. ROSENBLATT: Object to form.</p>

11 (Pages 38 to 41)

Joseph M. Carbone, M.D.

<p style="text-align: right;">Page 42</p> <p>1 THE DEPONENT: I guess if you're -- by</p> <p>2 reacting, you say inflammatory response, my answer</p> <p>3 would be yes.</p> <p>4 BY MR. JONES:</p> <p>5 Q. Does the woman's body ever stop attacking the</p> <p>6 TVT mesh while it's inside her body?</p> <p>7 MR. ROSENBLATT: Object to the term</p> <p>8 "attacking."</p> <p>9 THE DEPONENT: Well, I would say the same</p> <p>10 thing. If you define attacking as inflammatory</p> <p>11 response or the -- then, yes.</p> <p>12 BY MR. JONES:</p> <p>13 Q. The inflammatory response to the TVT mesh is</p> <p>14 not permanent. Correct?</p> <p>15 A. Correct.</p> <p>16 Q. When does the inflammatory response to the</p> <p>17 TVT mesh stop for a woman?</p> <p>18 MR. ROSENBLATT: Object to form.</p> <p>19 THE DEPONENT: The inflammatory response to</p> <p>20 the TVT mesh stops when the fibroblasts, the</p> <p>21 neutrophils, the macrophages lay down a collagenous --</p> <p>22 lay down new collagen incorporating the entire material</p> <p>23 so that the material itself is no longer internally</p> <p>24 exposed to the immune system.</p>	<p style="text-align: right;">Page 44</p> <p>1 told them no?</p> <p>2 MR. ROSENBLATT: I assume you're referring to</p> <p>3 the law firm?</p> <p>4 THE DEPONENT: When the law firm calls me?</p> <p>5 BY MR. JONES:</p> <p>6 Q. Sure. If that helps.</p> <p>7 A. Okay.</p> <p>8 Q. I'm not sure it does, but...</p> <p>9 A. No, not yet.</p> <p>10 Q. Okay. So in all the times that Ethicon or</p> <p>11 Ethicon's attorneys have contacted you to ask you to</p> <p>12 act as an expert in litigation matters, you've never</p> <p>13 turned them down. Correct?</p> <p>14 A. Yeah. I've had no reason to turn them down.</p> <p>15 Q. Yes or no?</p> <p>16 A. No.</p> <p>17 Q. As I understand it, you're working on a total</p> <p>18 of seven cases for Ethicon currently?</p> <p>19 A. No.</p> <p>20 Q. That was maybe a mistake earlier. Is it</p> <p>21 five?</p> <p>22 A. No. I mean --</p> <p>23 Q. How many cases are you working on for Ethicon</p> <p>24 currently?</p>
<p style="text-align: right;">Page 43</p> <p>1 BY MR. JONES:</p> <p>2 Q. Is it your understanding that occurs at about</p> <p>3 four to six weeks after implantation?</p> <p>4 A. You know, everybody's immune system is</p> <p>5 different.</p> <p>6 Q. Do you have any estimate when that stops, the</p> <p>7 inflammatory response? A range?</p> <p>8 A. Everybody's immune system is different.</p> <p>9 Q. Can't provide a range, as you sit here today?</p> <p>10 MR. ROSENBLATT: Object to form. Asked and</p> <p>11 answered.</p> <p>12 THE DEPONENT: Everybody's immune system is</p> <p>13 different.</p> <p>14 BY MR. JONES:</p> <p>15 Q. That's fair.</p> <p>16 Have you ever turned down a case when Ethicon</p> <p>17 called you to look at it?</p> <p>18 A. I don't understand what your question is.</p> <p>19 Q. Ethicon called you and says, "Hey,</p> <p>20 Dr. Carbone, we'd like you to look at some cases that</p> <p>21 are involved in litigation." You follow me?</p> <p>22 A. Oh, okay. Litigation cases, got it.</p> <p>23 Q. When Ethicon has asked you to act as an</p> <p>24 expert for them in litigation matters, have you ever</p>	<p style="text-align: right;">Page 45</p> <p>1 MR. ROSENBLATT: It's at least three times</p> <p>2 less than Dr. Rosenzweig.</p> <p>3 MR. JONES: That's fine.</p> <p>4 BY MR. JONES:</p> <p>5 Q. How many cases are you working on for</p> <p>6 Ethicon? Do you know?</p> <p>7 A. Well, yeah, I do, but I don't know how</p> <p>8 many -- well, one -- you know what I mean? Some of --</p> <p>9 Q. I don't know what you --</p> <p>10 A. -- your cases --</p> <p>11 Q. -- mean, honestly.</p> <p>12 A. I do. Well, let me explain --</p> <p>13 Q. Tell me how many cases you're working on</p> <p>14 currently for Ethicon.</p> <p>15 A. Five.</p> <p>16 Q. Five.</p> <p>17 A. I believe.</p> <p>18 Q. Okay. Are those cases laser cut or</p> <p>19 mechanical cut mesh?</p> <p>20 A. I believe them all to be -- depends on the</p> <p>21 time -- well, some of them are laser cut, some of them</p> <p>22 are mechanical cut. I don't recall the -- I don't</p> <p>23 recall the specific dates of the -- as I sit here</p> <p>24 today, trying to remember all the specific cases, I</p>

12 (Pages 42 to 45)

Joseph M. Carbone, M.D.

<p style="text-align: right;">Page 46</p> <p>1 don't remember the specific dates that the implants 2 were placed, so I don't remember whether they were 3 laser cut or mechanically cut. 4 Q. Okay. 5 A. I apologize. 6 Q. You'll be able to look at those cases, look 7 at the implant date, and determine whether they're 8 mechanical cut or laser cut mesh. Correct? 9 A. Yes. 10 Q. Okay. In these five cases that you offered 11 opinions in, in every single one of those five cases 12 you've made a determination that the Ethicon mesh is 13 not to blame for the injuries alleged. Correct? 14 A. I have made the opinion that the injuries -- 15 I'm sorry. What did you say? The injuries -- 16 Can you read back -- 17 MR. JONES: Can you read back that question? 18 Thank you. 19 We may need some more time. 20 THE DEPONENT: Okay. I apologize. 21 (Whereupon, the requested portion was read 22 back by the court reporter.) 23 THE DEPONENT: I have determined that the 24 injuries alleged were not due to any defect in the</p>	<p style="text-align: right;">Page 48</p> <p>1 A. It must pass through legal so I don't violate 2 any federal regulations, yes. 3 Q. Has there ever been a time when you've 4 created -- 5 Who creates the presentations that you give, 6 Ethicon or you, in your role as a consultant for 7 Ethicon? 8 A. Unfortunately, Ethicon. 9 Q. Unfortunately, Ethicon creates the 10 presentations you give in your role as a consultant for 11 Ethicon. Correct? 12 A. Yes. 13 Q. Why do you say "unfortunately"? 14 A. Because I like to use humor in my 15 presentations, and the presentations that come out of 16 legal are rather dry. 17 Q. That's right. You can blame the attorneys 18 for that. 19 Informed consent, let's talk about that. 20 Is it your understanding that if a patient 21 doesn't sign an informed consent form, they don't get 22 the surgery? 23 A. Well, who's operating? 24 Q. You are.</p>
<p style="text-align: right;">Page 47</p> <p>1 product. 2 BY MR. JONES: 3 Q. And in each of the five cases -- strike that. 4 In all of the cases that you're acting as an 5 expert for Ethicon in, you've determined the injuries 6 alleged are not due to a defect in Ethicon mesh 7 products. Correct? 8 A. Yes. 9 Q. Okay. I want to talk to you about some of 10 these presentations that you've given as a consultant 11 for Ethicon. 12 A. Okay. 13 Q. Is it true that every presentation that you 14 present, in your role as a consultant for Ethicon, must 15 be approved by Ethicon? 16 A. My understanding is it must be approved by 17 the FDA. It has to go through some sort of a legal 18 process that -- the Office of the Inspector General 19 approves it. 20 Q. Okay. I'm not asking about anything on the 21 FDA. 22 Yes or no, is it your understanding that when 23 you give a presentation as a consultant for Ethicon, 24 that material must be approved by Ethicon?</p>	<p style="text-align: right;">Page 49</p> <p>1 A. Me. I want to have a patient or a patient's 2 representative sign the informed consent before I 3 perform the surgery. 4 Q. A patient has to sign the informed consent 5 form before you will ever operate on them. Correct? 6 A. Before I will ever operate on them, yes. 7 Q. Have you heard of any physicians that operate 8 on a patient without informed consent forms? 9 A. I personally have not. 10 Q. Okay. Have you ever compared your consent 11 form to any other doctor's informed consent form for 12 the treatment of stress urinary incontinence? 13 A. I'm trying to think if any of the literature 14 I reviewed actually, specifically listed the 15 informed -- listed the actual informed content forms. 16 But other than that, I've never actually gone to 17 another doctor and asked about their informed consent 18 forms, no. 19 Q. Are you aware of any classifications on pore 20 size besides Amid? 21 A. I'm sure I've reviewed others, but the Amid 22 is the one I'm most familiar with. 23 Q. Are you aware of any pore size 24 classifications have that been released by the IUGA?</p>

13 (Pages 46 to 49)

Joseph M. Carbone, M.D.

Page 50	Page 52
<p>1 A. Like I said, I'm sure I've reviewed some, but</p> <p>2 the one I'm most familiar with is Amid.</p> <p>3 Q. Okay. Is it fair to say you're most familiar</p> <p>4 with the Amid classification, but there are probably</p> <p>5 other classifications that exist on pore size related</p> <p>6 to mesh?</p> <p>7 A. I can't say that with certainty.</p> <p>8 Q. You can't say with certainty whether there's</p> <p>9 any mesh classification on pore size besides Amid.</p> <p>10 Correct?</p> <p>11 A. Correct.</p> <p>12 Q. Ethicon has never sent you any documents or</p> <p>13 medical literature related to a pore size</p> <p>14 classification other than Amid. Correct?</p> <p>15 A. I don't recall.</p> <p>16 Q. You don't know one way or the other?</p> <p>17 A. I don't recall.</p> <p>18 Q. Okay. Do you customarily implant TVT mesh in</p> <p>19 obese patients?</p> <p>20 A. Yes.</p> <p>21 Q. Do you have any --</p> <p>22 Has Ethicon ever told you not to put TVT mesh</p> <p>23 in obese patients?</p> <p>24 A. No.</p>	<p>1 Q. Pain?</p> <p>2 A. No.</p> <p>3 Q. Dyspareunia?</p> <p>4 A. Yes.</p> <p>5 Q. Dyspareunia?</p> <p>6 A. Yes.</p> <p>7 Q. Did you remove all the mesh?</p> <p>8 A. No.</p> <p>9 Q. Why not?</p> <p>10 A. Because I removed the exposed mesh.</p> <p>11 Q. Trimmed it?</p> <p>12 A. No. I dissected it free and tunneled under,</p> <p>13 excised a segment of mesh, oversewed the vaginal</p> <p>14 epithelium, and removed the mesh.</p> <p>15 Q. When's the last time you removed an Ethicon</p> <p>16 mesh product?</p> <p>17 A. Probably last year.</p> <p>18 Q. Okay. Do you recall which Ethicon mesh</p> <p>19 product it was?</p> <p>20 A. No, I don't.</p> <p>21 Q. Okay. Have you ever removed a TVT mesh</p> <p>22 product from a woman because of an erosion?</p> <p>23 A. Yes.</p> <p>24 Q. Have you ever removed a TVT mesh product from</p>
Page 51	Page 53
<p>1 Q. Are you aware of any Ethicon marketing</p> <p>2 materials that specifically target obese women?</p> <p>3 A. "Targeting"? I'm not aware of any Ethicon</p> <p>4 materials where they specifically target obese women.</p> <p>5 Q. Okay. Are you aware of any Ethicon materials</p> <p>6 that state -- that recommends using TVT mesh in obese</p> <p>7 patients?</p> <p>8 A. Recommends using? No.</p> <p>9 Q. Okay. You stated the other day you've</p> <p>10 removed about 50 to 40 mesh products in women.</p> <p>11 Correct?</p> <p>12 A. Probably about that.</p> <p>13 Q. Mostly Ethicon mesh products. Correct?</p> <p>14 A. Yes.</p> <p>15 Q. What were the indications for some of those</p> <p>16 removals?</p> <p>17 A. Most of the indications were erosion.</p> <p>18 Q. When's the last time you did a removal</p> <p>19 surgery?</p> <p>20 A. Tuesday.</p> <p>21 Q. Tuesday? What product was it?</p> <p>22 A. Spark.</p> <p>23 Q. Spark? Erosion?</p> <p>24 A. Yes.</p>	<p>1 a woman because of pain?</p> <p>2 A. No.</p> <p>3 Q. Have you ever removed a TVT mesh product from</p> <p>4 a woman because of dyspareunia?</p> <p>5 A. No.</p> <p>6 Q. Have you ever removed a TVT mesh product from</p> <p>7 a woman for any other reason besides erosion?</p> <p>8 A. No.</p> <p>9 Q. Have you ever removed any Ethicon mesh</p> <p>10 product from a woman because of pain?</p> <p>11 A. I'm sorry. How was that different?</p> <p>12 Q. Have you ever removed any Ethicon mesh</p> <p>13 product from a woman because of pain?</p> <p>14 A. Specifically because of pain without erosion?</p> <p>15 No.</p> <p>16 Q. Okay. You have removed an Ethicon mesh</p> <p>17 product from a woman because of an erosion and pain.</p> <p>18 Correct?</p> <p>19 A. The indication I have for removing the mesh</p> <p>20 product is the erosion.</p> <p>21 Q. Okay. Am I correct in saying, on at least</p> <p>22 one occasion when you removed an Ethicon mesh product,</p> <p>23 the woman experienced an erosion and pain?</p> <p>24 A. Yes.</p>

14 (Pages 50 to 53)

Joseph M. Carbone, M.D.

Page 54	Page 56
<p>1 Q. Should doctors be able to rely on the</p> <p>2 warnings in the TVT IFU?</p> <p>3 A. I don't think they should solely rely on the</p> <p>4 warnings --</p> <p>5 Q. That's not what I asked.</p> <p>6 A. -- but yes, they should rely on the warnings.</p> <p>7 Q. I'll ask the question again.</p> <p>8 A. The warnings should be reliable.</p> <p>9 Q. Should doctors be able to rely on the warning</p> <p>10 statements in the IFU, TVT IFU, yes or no?</p> <p>11 MR. ROSENBLATT: Objection. Asked and</p> <p>12 answered.</p> <p>13 MR. JONES: No, it wasn't.</p> <p>14 MR. ROSENBLATT: He said that they shouldn't</p> <p>15 solely rely on them.</p> <p>16 BY MR. JONES:</p> <p>17 Q. Answer the question yes or no.</p> <p>18 A. Should they -- repeat the question.</p> <p>19 Q. I know. I'm sorry.</p> <p>20 A. You can have more time.</p> <p>21 Q. I'm sorry.</p> <p>22 A. You can have as much time as you --</p> <p>23 Q. I appreciate that.</p> <p>24 Should doctors be able to rely --</p>	<p>1 Q. The removal of the Ethicon mesh product</p> <p>2 relieved the symptoms that led to the mesh removal.</p> <p>3 Correct?</p> <p>4 A. Yes.</p> <p>5 Q. Have you seen patients that have been a</p> <p>6 plaintiff with an Ethicon mesh product who have had</p> <p>7 recurring erosions?</p> <p>8 A. No.</p> <p>9 Q. What's the mesh look like -- what's the</p> <p>10 Ethicon mesh look like when you take it out of the</p> <p>11 patient?</p> <p>12 MR. ROSENBLATT: Objection to form.</p> <p>13 THE DEPONENT: I can't really answer that</p> <p>14 because when I remove the mesh, it's incorporated into</p> <p>15 the tissue. So except for the small segment that has</p> <p>16 been exposed, I can't see any more of the mesh. It's</p> <p>17 been incorporated into the tissue that I removed.</p> <p>18 BY MR. JONES:</p> <p>19 Q. Okay. So the mesh that's in -- that has</p> <p>20 tissue incorporated through it, you leave inside the</p> <p>21 patient. Correct?</p> <p>22 A. No, I didn't say that. I said --</p> <p>23 Q. You can't see the mesh because it's got</p> <p>24 tissue incorporated in it and covering it. Correct?</p>
Page 55	Page 57
<p>1 I'm not going to take more time. Strike</p> <p>2 that.</p> <p>3 Should doctors be able to rely on the</p> <p>4 warnings in the TVT IFU, yes or no?</p> <p>5 MR. ROSENBLATT: Objection. Asked and</p> <p>6 answered.</p> <p>7 You can answer yes or no, if you can. If</p> <p>8 not, say you can't answer that.</p> <p>9 THE DEPONENT: I can't answer that as a</p> <p>10 yes-or-no question.</p> <p>11 BY MR. JONES:</p> <p>12 Q. You can't answer yes or no, whether doctors</p> <p>13 should be able to rely on the warnings in the TVT IFU?</p> <p>14 MR. ROSENBLATT: He's already explained his</p> <p>15 answer.</p> <p>16 MR. JONES: Paul --</p> <p>17 THE DEPONENT: They should.</p> <p>18 BY MR. JONES:</p> <p>19 Q. They should be able to rely?</p> <p>20 A. Yes.</p> <p>21 Q. Okay. In any of these Ethicon mesh products</p> <p>22 that you reviewed for women, did the women continue to</p> <p>23 experience complications after the removal?</p> <p>24 A. No.</p>	<p>1 A. But that doesn't stay in the patient. That</p> <p>2 comes out of the patient.</p> <p>3 Q. Okay. So you take -- when you remove Ethicon</p> <p>4 mesh products from women, you remove mesh that has</p> <p>5 tissue incorporated into it. Correct?</p> <p>6 A. Yes.</p> <p>7 Q. Okay. Is there -- are there any nerves</p> <p>8 running through the tissue that's incorporated into the</p> <p>9 mesh when you remove it from a patient?</p> <p>10 A. How to answer that?</p> <p>11 Not that I'm aware of.</p> <p>12 Q. Are removal surgeries involving Ethicon mesh</p> <p>13 products painful for women?</p> <p>14 MR. ROSENBLATT: Objection to form.</p> <p>15 THE DEPONENT: It depends on the -- well --</p> <p>16 MR. ROSENBLATT: Are you asking about --</p> <p>17 THE DEPONENT: No, no. I mean, let me think</p> <p>18 for a moment.</p> <p>19 Repeat the question.</p> <p>20 MR. JONES: Okay. What time is it? Are we</p> <p>21 ready?</p> <p>22 MR. FAES: It's 6:45. She just dialed in.</p> <p>23 MR. JONES: Let's go off the record.</p> <p>24 (Whereupon, a recess was taken from 6:47 p.m.</p>

15 (Pages 54 to 57)

Joseph M. Carbone, M.D.

<p style="text-align: right;">Page 58</p> <p>1 to 7:04 a.m.)</p> <p>2 BY MR. JONES:</p> <p>3 Q. All right, Doctor. Are you ready to proceed?</p> <p>4 A. Yes, I am.</p> <p>5 Q. And just for the record, I only have two</p> <p>6 hours of time, so I'd appreciate it if you'd use the</p> <p>7 time as efficiently as possible, and if we have some</p> <p>8 delays like we had earlier in the night, I'm going to</p> <p>9 have to ask for additional time.</p> <p>10 Do you understand that?</p> <p>11 MR. ROSENBLATT: You mean when you were not</p> <p>12 asking about TVT-O?</p> <p>13 MR. JONES: All questions have been related</p> <p>14 to TVT-O. We'll go back and look at the transcript</p> <p>15 from last week, if you want, Paul, about how attorneys</p> <p>16 ask questions from your law firm, if we need to.</p> <p>17 BY MR. JONES:</p> <p>18 Q. Do you understand that, Doctor?</p> <p>19 A. Yes.</p> <p>20 Q. Let's proceed.</p> <p>21 Do you agree that the primary source of</p> <p>22 information about the risk associated with TVT mesh</p> <p>23 comes from Ethicon?</p> <p>24 A. No.</p>	<p style="text-align: right;">Page 60</p> <p>1 A. Okay. Yes.</p> <p>2 Q. Yes. Ethicon knows more about the TVT design</p> <p>3 features than you do?</p> <p>4 A. Not in their clinical use, but with respect</p> <p>5 to their design and their biomechanical -- their</p> <p>6 engineering, yes.</p> <p>7 Q. The design process involved with the TVT line</p> <p>8 of products, Ethicon is more familiar with the design</p> <p>9 process than you are. Correct?</p> <p>10 A. With the design -- with the corporate design</p> <p>11 process, they are more familiar.</p> <p>12 Q. So the process that involves taking a product</p> <p>13 from its initial design all the way up until it's</p> <p>14 marketed to doctors, Ethicon is more familiar with that</p> <p>15 than you are. Correct?</p> <p>16 MR. ROSENBLATT: Object to form.</p> <p>17 THE DEPONENT: You didn't specify --</p> <p>18 BY MR. JONES:</p> <p>19 Q. TVT. We're talking about TVT.</p> <p>20 A. Thank you.</p> <p>21 Yes.</p> <p>22 Q. Okay. How much do you -- you get paid per</p> <p>23 TVT Exact you put in a patient?</p> <p>24 A. The practice gets a payment for the billing</p>
<p style="text-align: right;">Page 59</p> <p>1 Q. Do you agree that Ethicon knows more about</p> <p>2 the design features of TVT mesh than doctors?</p> <p>3 A. Which doctors?</p> <p>4 Q. All doctors.</p> <p>5 A. The doctors in Ethicon?</p> <p>6 Q. All doctors not employed by Ethicon.</p> <p>7 MR. ROSENBLATT: Object to form.</p> <p>8 THE DEPONENT: I don't know.</p> <p>9 BY MR. JONES:</p> <p>10 Q. You don't know whether Ethicon knows more</p> <p>11 about the design features of the TVT product than</p> <p>12 doctors not employed by Ethicon. Correct?</p> <p>13 MR. ROSENBLATT: Object to form.</p> <p>14 THE DEPONENT: I don't know everything that</p> <p>15 doctors not employed by Ethicon know.</p> <p>16 BY MR. JONES:</p> <p>17 Q. Do you think Ethicon knows more about the</p> <p>18 design features of the TVT than you?</p> <p>19 MR. ROSENBLATT: Object to form.</p> <p>20 THE DEPONENT: The TVT product, are you</p> <p>21 talking specifically the Retropubic?</p> <p>22 BY MR. JONES:</p> <p>23 Q. I'm talking about them all. I didn't break</p> <p>24 it up.</p>	<p style="text-align: right;">Page 61</p> <p>1 of the procedure. I...</p> <p>2 You mean with respect to -- from Ethicon? Or</p> <p>3 can I ask, are you talking about from Ethicon, or are</p> <p>4 you talking about from Medicare or the insurance</p> <p>5 companies?</p> <p>6 MR. ROSENBLATT: If you don't understand the</p> <p>7 question --</p> <p>8 THE DEPONENT: I don't understand the</p> <p>9 question.</p> <p>10 MR. ROSENBLATT: -- ask him to clarify.</p> <p>11 BY MR. JONES:</p> <p>12 Q. Answer both.</p> <p>13 A. I don't believe that the practice gets any</p> <p>14 money from Ethicon. They get it from the insurance</p> <p>15 companies.</p> <p>16 Q. How much does the insurance company pay your</p> <p>17 practice per Ethicon sling you put in?</p> <p>18 A. I don't know.</p> <p>19 Q. You have no idea whatsoever how much your</p> <p>20 clinic gets paid per Ethicon sling you put in?</p> <p>21 A. No.</p> <p>22 Q. How many members are part of your practice?</p> <p>23 A. I mean, we employ quite a few people. What</p> <p>24 do you mean by members?</p>

16 (Pages 58 to 61)

Joseph M. Carbone, M.D.

Page 62	Page 64
<p>1 Q. I mean partners.</p> <p>2 A. Urology partners or --</p> <p>3 Q. Urology partners.</p> <p>4 A. Urology partners, there are two.</p> <p>5 Q. Two urology partners at your practice?</p> <p>6 A. Yes.</p> <p>7 Q. Including yourself?</p> <p>8 A. Yes.</p> <p>9 Q. How many other partners?</p> <p>10 A. I'm counting. Six.</p> <p>11 Q. Six total partners?</p> <p>12 A. No.</p> <p>13 Q. Eight total partners?</p> <p>14 A. It's supposed to be seven. Seven total</p> <p>15 partners.</p> <p>16 Q. Okay. So we've got seven total partners at</p> <p>17 your practice?</p> <p>18 A. Yes.</p> <p>19 Q. So when you put in an Ethicon mesh sling, the</p> <p>20 proceeds from that Ethicon mesh sling you put in are</p> <p>21 split between seven partners?</p> <p>22 A. Yes -- eight.</p> <p>23 Q. Okay.</p> <p>24 A. Eight total partners.</p>	<p>1 percentage?</p> <p>2 BY MR. JONES:</p> <p>3 Q. Do you understand what the word "frequency"</p> <p>4 means?</p> <p>5 A. It depends on --</p> <p>6 Q. You don't understand what the word</p> <p>7 "frequency" means?</p> <p>8 A. I don't understand how you're using it, no.</p> <p>9 Q. Okay. Do you understand what the word</p> <p>10 "severity" means?</p> <p>11 A. It's a scale, but it's a very subjective</p> <p>12 scale.</p> <p>13 Q. Do you believe -- have you ever reviewed the</p> <p>14 deposition testimony of Piet Hinoul? You don't know</p> <p>15 who he is. Right?</p> <p>16 Do you know who Piet Hinoul is, Dr. Carbone,</p> <p>17 yes or no?</p> <p>18 A. I'm trying to answer your other question.</p> <p>19 Q. I'll strike that question. I'll withdraw it.</p> <p>20 The question pending is: Do you know who</p> <p>21 Dr. Piet Hinoul is?</p> <p>22 A. No.</p> <p>23 Q. Okay. Do you know who Catherine Beath is?</p> <p>24 A. No.</p>
Page 63	Page 65
<p>1 Q. I'm not going to go back to it.</p> <p>2 A. Thank you.</p> <p>3 Q. Do you consider yourself an expert on TVT</p> <p>4 warning statements, yes or no?</p> <p>5 A. Yes. I have read the warning statements. I</p> <p>6 have taught physicians regarding warnings about the</p> <p>7 procedure. I have read the warning statements</p> <p>8 themselves. So I'm uniquely an expert regarding the</p> <p>9 warning statements.</p> <p>10 Q. Do you know who Dr. Piet Hinoul is?</p> <p>11 A. I'm sorry?</p> <p>12 Q. Do you know who Dr. Piet Hinoul is?</p> <p>13 A. No.</p> <p>14 Q. Should the TVT IFU warning statement include</p> <p>15 the frequency of the risks associated with the TVT</p> <p>16 device, yes or no?</p> <p>17 A. Which risks?</p> <p>18 Q. All of them. Yes or no. All of them. I'm</p> <p>19 not distinguishing between risks.</p> <p>20 A. No. It should be the risks specific to the</p> <p>21 TVT device, not all pelvic surgery.</p> <p>22 Q. Okay. So frequency of the risk you just</p> <p>23 described not required to be in a TVT IFU. Correct?</p> <p>24 MR. ROSENBLATT: You mean like a certain</p>	<p>1 Q. Have you ever assisted a medical device</p> <p>2 company in drafting an IFU?</p> <p>3 A. No.</p> <p>4 Q. Do you have any patents on any medical</p> <p>5 devices?</p> <p>6 A. No.</p> <p>7 Q. Have you ever helped a medical device company</p> <p>8 design a mesh product intended to treat stress urinary</p> <p>9 incontinence?</p> <p>10 A. Are we speaking about Ethicon or any --</p> <p>11 Q. Ethicon.</p> <p>12 A. No.</p> <p>13 Q. Ethicon's never asked you to help them design</p> <p>14 a mesh product for the treatment of stress urinary</p> <p>15 incontinence?</p> <p>16 A. No.</p> <p>17 Q. Do you agree that Ethicon did not design the</p> <p>18 TVT mesh to fray?</p> <p>19 A. You put a negative in there. I apologize.</p> <p>20 Q. Do you agree that Ethicon did not design the</p> <p>21 TVT mesh to fray when used properly?</p> <p>22 A. Designed the TVT mesh to not fray?</p> <p>23 MR. JONES: Can you please read back the</p> <p>24 question for the doctor?</p>

17 (Pages 62 to 65)

Joseph M. Carbone, M.D.

Page 66	Page 68
<p>1 THE DEPONENT: Yes. I apologize.</p> <p>2 (Whereupon, the requested portion was read</p> <p>3 back by the court reporter.)</p> <p>4 MR. JONES: Any objection, Paul?</p> <p>5 MR. ROSENBLATT: Yeah, the last time you</p> <p>6 phrased the question was "when used properly."</p> <p>7 THE COURT REPORTER: I apologize. Yes, he</p> <p>8 did. I read the wrong question back.</p> <p>9 MR. ROSENBLATT: She's not reading back the</p> <p>10 right question.</p> <p>11 THE COURT REPORTER: I read one previous. I</p> <p>12 apologize.</p> <p>13 (Whereupon, the last question was read back</p> <p>14 by the court reporter.)</p> <p>15 THE DEPONENT: Yes.</p> <p>16 MR. ROSENBLATT: Those are two different</p> <p>17 questions.</p> <p>18 BY MR. JONES:</p> <p>19 Q. "Yes" is the answer?</p> <p>20 A. Yes.</p> <p>21 Q. Thanks for answering.</p> <p>22 You agree that Ethicon did not design the TVT</p> <p>23 mesh to lose particles when used properly?</p> <p>24 A. Yes.</p>	<p>1 BY MR. JONES:</p> <p>2 Q. Yes or no, Doctor.</p> <p>3 A. I was referring to the analysis that I made</p> <p>4 being related to the high-level literature regarding</p> <p>5 fraying of the mesh.</p> <p>6 Q. I've got to strike your answer. You're not</p> <p>7 responsive -- you're not responding to my question at</p> <p>8 all.</p> <p>9 MR. ROSENBLATT: Stop cutting him off.</p> <p>10 BY MR. JONES:</p> <p>11 Q. Here's my question, Doctor.</p> <p>12 A. I have not come across any literature</p> <p>13 discussing fraying of the mesh.</p> <p>14 MR. JONES: Okay. I move to strike.</p> <p>15 BY MR. JONES:</p> <p>16 Q. I'm not asking about literature whatsoever.</p> <p>17 A. Okay.</p> <p>18 Q. Listen to my question, please.</p> <p>19 Have you ever done an analysis of the</p> <p>20 complaints Ethicon's received relating to TVT mesh</p> <p>21 fraying, yes or no?</p> <p>22 A. Of the complaints Ethicon's received? No.</p> <p>23 Q. Thank you.</p> <p>24 Have you ever done an analysis of the</p>
Page 67	Page 69
<p>1 Q. Do you agree Ethicon TVT mesh fraying is an</p> <p>2 unintended consequence?</p> <p>3 A. In the clinical setting?</p> <p>4 Q. Yes.</p> <p>5 A. When used properly?</p> <p>6 Q. Yes.</p> <p>7 A. Then TVT fraying doesn't occur.</p> <p>8 Q. Never. Right?</p> <p>9 A. In my clinical experience, it doesn't occur.</p> <p>10 Q. Have you ever attempted to do an analysis of</p> <p>11 complaints Ethicon's received related to TVT mesh</p> <p>12 fraying?</p> <p>13 A. No. I've done an analysis regarding the</p> <p>14 available literature and --</p> <p>15 Q. The answer's no?</p> <p>16 A. -- and I haven't --</p> <p>17 MR. ROSENBLATT: Don't cut him off.</p> <p>18 MR. JONES: I just --</p> <p>19 BY MR. JONES:</p> <p>20 Q. Here's the question.</p> <p>21 Read back the question again, please.</p> <p>22 (Whereupon, the requested portion was read</p> <p>23 back by the court reporter.)</p> <p>24</p>	<p>1 complaints Ethicon's received related to TVT mesh</p> <p>2 losing particles, yes or no?</p> <p>3 A. Again, I will have to refer to my analysis of</p> <p>4 the literature --</p> <p>5 Q. No. Motion to strike, Doctor.</p> <p>6 A. -- and I will answer your specific question.</p> <p>7 Q. Thank you.</p> <p>8 A. No.</p> <p>9 Q. Thank you.</p> <p>10 So the answer's no. Correct?</p> <p>11 A. Not of the --</p> <p>12 Q. Just listen to the questions and answer them.</p> <p>13 Okay, Doctor?</p> <p>14 Have you ever done an analysis of Ethicon</p> <p>15 complaints received related to TVT mesh losing</p> <p>16 particles, yes or no?</p> <p>17 A. You already asked that question.</p> <p>18 Q. Yes or no?</p> <p>19 A. I already answered that question. No. No.</p> <p>20 Q. Thanks.</p> <p>21 Have you ever done an analysis of the</p> <p>22 complaints Ethicon's received related to TVT mesh</p> <p>23 curling, yes or no?</p> <p>24 A. With the same said stipulation, no.</p>

18 (Pages 66 to 69)

Joseph M. Carbone, M.D.

<p style="text-align: right;">Page 70</p> <p>1 Q. Per the consultant agreements you signed with</p> <p>2 Ethicon, you were not allowed to express your personal</p> <p>3 opinions with Ethicon products unless Ethicon approved</p> <p>4 the statement. Correct?</p> <p>5 A. If I did, the --</p> <p>6 MR. ROSENBLATT: Object to form.</p> <p>7 THE DEPONENT: -- the Office of the Inspector</p> <p>8 General would come down on me and the company.</p> <p>9 BY MR. JONES:</p> <p>10 Q. Yes or no, per the consultant agreement you</p> <p>11 signed, you were not allowed to express your personal</p> <p>12 opinion about Ethicon products unless Ethicon approved</p> <p>13 the statement. Correct?</p> <p>14 MR. ROSENBLATT: Object to form. I don't</p> <p>15 know if that's what it actually says.</p> <p>16 THE DEPONENT: Which products?</p> <p>17 BY MR. JONES:</p> <p>18 Q. That's the question. I'm not distinguishing</p> <p>19 products. All products, Doctor.</p> <p>20 A. I don't --</p> <p>21 MR. ROSENBLATT: Do you have the exact</p> <p>22 language, Nate?</p> <p>23 MR. JONES: No, I don't. It's not from the</p> <p>24 exact language either, Paul, but thanks for asking.</p>	<p style="text-align: right;">Page 72</p> <p>1 Ethicon about the terms involved in the consulting</p> <p>2 contracts you signed?</p> <p>3 A. I remember early on in 2003 I had my attorney</p> <p>4 review, but he didn't have issues. So I never saw the</p> <p>5 need to have any further negotiations, no.</p> <p>6 MR. JONES: Okay. I'm going to go ahead and</p> <p>7 mark as Exhibit 8, I believe, we're on --</p> <p>8 THE COURT REPORTER: Let me just ask you,</p> <p>9 this one has an 8 on it.</p> <p>10 MR. JONES: We'll mark it Exhibit 9 then.</p> <p>11 (Consulting Agreement, Joseph M. Carbone,</p> <p>12 M.D., June 10, 2002, ETH.MESH.03605451-03605456, marked</p> <p>13 for identification as Carbone Deposition Exhibit</p> <p>14 No. 9.)</p> <p>15 MR. JONES: I will hand you Exhibit 9.</p> <p>16 MR. ROSENBLATT: Thanks.</p> <p>17 BY MR. JONES:</p> <p>18 Q. Now, we've got limited time and we're already</p> <p>19 going back and forth about issues, so take a second to</p> <p>20 look over this, but I'm going to tell you I'm not going</p> <p>21 to ask you questions about the entirety of this</p> <p>22 contract.</p> <p>23 A. If you can point to the --</p> <p>24 Q. I will.</p>
<p style="text-align: right;">Page 71</p> <p>1 THE DEPONENT: I haven't reviewed recently a</p> <p>2 contract that I signed with Ethicon.</p> <p>3 BY MR. JONES:</p> <p>4 Q. Here's the question. Yes or no, per the</p> <p>5 consultant agreement signed, you were not allowed to</p> <p>6 express your personal opinion about Ethicon products</p> <p>7 unless Ethicon approved the statement. Correct?</p> <p>8 MR. ROSENBLATT: Object to form. Lack of</p> <p>9 foundation.</p> <p>10 THE DEPONENT: The last time I've signed a</p> <p>11 contract was in, I guess, 2012, which would be three</p> <p>12 years ago, and I don't recall the specifics.</p> <p>13 BY MR. JONES:</p> <p>14 Q. How -- explain -- did you review the terms of</p> <p>15 a contract before you signed it with Ethicon?</p> <p>16 A. Yeah. I read them.</p> <p>17 Q. Did you have your attorney review the terms</p> <p>18 of the contract before you signed it?</p> <p>19 A. Not always.</p> <p>20 Q. Not always?</p> <p>21 A. Unh-unh.</p> <p>22 Q. Sometimes you did though?</p> <p>23 A. Sometimes I did.</p> <p>24 Q. Was there ever a negotiation process with</p>	<p style="text-align: right;">Page 73</p> <p>1 A. -- specific line, I'll be --</p> <p>2 Q. I will. How about this? Let's focus --</p> <p>3 A. -- and section.</p> <p>4 Q. -- on the first page.</p> <p>5 A. First page.</p> <p>6 Q. This is a contract dated June 10, 2002.</p> <p>7 Correct?</p> <p>8 A. Yes.</p> <p>9 Q. And the top right -- top left corner,</p> <p>10 Joseph M. Carbone, M.D., is listed. Correct?</p> <p>11 A. Yes.</p> <p>12 Q. Do you recognize this as a consulting</p> <p>13 agreement you would have reviewed in 2002?</p> <p>14 A. Yes.</p> <p>15 Q. Okay. Okay. First page, paragraph 2, "Any</p> <p>16 confidential information acquired by consultant from</p> <p>17 Ethicon concerning existing or contemplated machines,</p> <p>18 products, processes, techniques, or know-how, or any</p> <p>19 information or data developed pursuant to the</p> <p>20 performance of the consulting services below, shall not</p> <p>21 be disclosed by consultant to others."</p> <p>22 Did I read that correctly?</p> <p>23 A. You read that exactly.</p> <p>24 Q. Does this indicate that --</p>

19 (Pages 70 to 73)

Joseph M. Carbone, M.D.

Page 74	Page 76
<p>1 MR. ROSENBLATT: For the purposes of</p> <p>2 completeness, it says "for the consultant's own</p> <p>3 benefit." I just wanted to read the rest of that.</p> <p>4 MR. JONES: Good for you.</p> <p>5 BY MR. JONES:</p> <p>6 Q. So did I read that correctly, the portion</p> <p>7 that I read though, Doctor?</p> <p>8 A. The portion that you read, you read</p> <p>9 correctly.</p> <p>10 Q. Okay. Did you ever disclose confidential</p> <p>11 information that you learned in your role as a</p> <p>12 consultant with Ethicon with anyone outside of Ethicon?</p> <p>13 A. I did not, for my own benefit, without the</p> <p>14 written consent of Ethicon.</p> <p>15 Q. Okay. Did you ever disclose it in any other</p> <p>16 capacity with written consent?</p> <p>17 A. I'm sorry?</p> <p>18 Q. Did you ever ask for written consent from</p> <p>19 Ethicon to disclose confidential information about</p> <p>20 their products?</p> <p>21 A. No, I never asked for written consent.</p> <p>22 Q. Okay. Go ahead and turn to page 2.</p> <p>23 A. 2.</p> <p>24 Q. Skip down, 7-B.</p>	<p>1 A. Yes.</p> <p>2 Q. Does that correctly state the way that you</p> <p>3 were paid by Ethicon for your preceptorships?</p> <p>4 A. Yes.</p> <p>5 Q. So for each additional surgeon that attended</p> <p>6 a preceptorship, you got another \$500. Correct?</p> <p>7 A. For preceptorships, not cadaveric labs.</p> <p>8 Q. Okay. For each additional surgeon that</p> <p>9 attended a preceptorship, you got an additional \$500</p> <p>10 from Ethicon. Correct? Yes or no.</p> <p>11 A. For each -- for preceptorships, \$1,500 for</p> <p>12 the first surgeon trained, plus \$500 for each</p> <p>13 additional surgeon, yes.</p> <p>14 Q. Got to ask the question again. Yes or no --</p> <p>15 it's just for the record, okay?</p> <p>16 A. Yes.</p> <p>17 Q. Yes is your answer?</p> <p>18 A. Yes.</p> <p>19 Q. Now, skip down to 9-B.</p> <p>20 A. 9-B.</p> <p>21 Q. As in "boy."</p> <p>22 "For events requiring a full day, eight or</p> <p>23 more hours away from office hospital, \$3,000 per day."</p> <p>24 Did I read that correctly?</p>
Page 75	Page 77
<p>1 A. I'm sorry. 7-D or B?</p> <p>2 Q. 7-D, as in "dog."</p> <p>3 A. Okay.</p> <p>4 Q. "Preceptor agrees to use only</p> <p>5 corporate-approved materials for didactic</p> <p>6 presentation."</p> <p>7 Did I read that correctly?</p> <p>8 A. That's what it says.</p> <p>9 Q. Was it your understanding that you were to</p> <p>10 only use corporate-approved materials in your</p> <p>11 professional education?</p> <p>12 A. Yes, sir.</p> <p>13 Q. Skip down to 8, Roman numeral I.</p> <p>14 Did you use the J&J travel department when</p> <p>15 you traveled in your role as a consultant for Ethicon?</p> <p>16 A. Yes.</p> <p>17 Q. Did Ethicon always reimburse you for your</p> <p>18 travel in your role as a consultant for Ethicon?</p> <p>19 A. To the best of my recollection, yes.</p> <p>20 Q. Turn to page 3. Skip down to 9-A.</p> <p>21 "For preceptorships, \$1,500 for the first</p> <p>22 surgeon trained, plus \$500 for each additional</p> <p>23 surgeon."</p> <p>24 Did I read that correctly?</p>	<p>1 A. Per day, yes.</p> <p>2 Q. Was it your understanding you got paid \$3,000</p> <p>3 per day for your role as a consultant for Ethicon?</p> <p>4 A. Cadaveric labs, teller surgery, and</p> <p>5 proctorships, yes.</p> <p>6 Q. Okay. Skip down to 9-D.</p> <p>7 "Under no circumstances shall Ethicon's</p> <p>8 obligation under this agreement exceed \$75,000 for the</p> <p>9 term of this agreement."</p> <p>10 Did I read that correctly?</p> <p>11 A. Yes.</p> <p>12 Q. Did you ever recruit physicians to be part of</p> <p>13 preceptorships for Ethicon?</p> <p>14 A. No.</p> <p>15 Q. Do you -- do you understand there was an</p> <p>16 incentive for more surgeons to participate in your</p> <p>17 preceptorships, based upon the payment scale provided</p> <p>18 by Ethicon?</p> <p>19 A. If you're motivated by that thing, but</p> <p>20 incentive is a very personal issue.</p> <p>21 Q. More -- the more surgeons who attended your</p> <p>22 preceptorships, the more you got paid. Correct?</p> <p>23 MR. ROSENBLATT: Object to form.</p> <p>24 THE DEPONENT: I'm sorry. Again?</p>

20 (Pages 74 to 77)

Joseph M. Carbone, M.D.

Page 78	Page 80
<p>1 BY MR. JONES:</p> <p>2 Q. The more surgeons who attended a</p> <p>3 preceptorship that you conducted, the more money</p> <p>4 Ethicon paid you. Correct?</p> <p>5 A. Correct.</p> <p>6 Q. You can put that one away, Doctor.</p> <p>7 A. Sure.</p> <p>8 MR. JONES: Exhibit 9 --</p> <p>9 MR. ROSENBLATT: 10.</p> <p>10 MR. JONES: -- 10. Thanks, Paul.</p> <p>11 Can't give you my copy.</p> <p>12 THE DEPONENT: Sorry.</p> <p>13 (Consulting Agreement, Joseph M. Carbone,</p> <p>14 M.D., December 22, 2003, ETH.MESH.16260588-16260593,</p> <p>15 marked for identification as Carbone Deposition Exhibit</p> <p>16 No. 10.)</p> <p>17 BY MR. JONES:</p> <p>18 Q. Does this look like a 2003 consulting</p> <p>19 agreement between yourself and Ethicon, Dr. Carbone?</p> <p>20 A. Yes.</p> <p>21 Q. Go ahead and turn to page 3. I'm going to</p> <p>22 focus on 9-D, as in "dog."</p> <p>23 "Under no circumstances shall Ethicon's</p> <p>24 obligation under this agreement exceed \$100,000 for the</p>	<p>1 Did I read that correctly?</p> <p>2 A. You left out "the company."</p> <p>3 Q. So I didn't read that correctly, is that what</p> <p>4 you're saying?</p> <p>5 A. No, you didn't.</p> <p>6 Q. Okay. "Ethicon, the company, is pleased that</p> <p>7 you have agreed to serve as a faculty member at</p> <p>8 training meetings conducted by the company for its</p> <p>9 sales force representatives (the training services)."</p> <p>10 Did I read that correctly?</p> <p>11 A. Yes.</p> <p>12 Q. Okay. Do you recall helping train the sales</p> <p>13 force at Ethicon?</p> <p>14 A. Yes.</p> <p>15 Q. Okay. And so between the time period of 2003</p> <p>16 to 2012, you helped Ethicon train its sales force.</p> <p>17 Correct?</p> <p>18 A. Well, this is a contract from 2006.</p> <p>19 Q. Between the years 2002 to 2003 to 2012, at</p> <p>20 different times you helped Ethicon train its sales</p> <p>21 force. Correct?</p> <p>22 MR. ROSENBLATT: Object to form.</p> <p>23 THE DEPONENT: I don't understand. I can say</p> <p>24 that at some time -- I don't --</p>
Page 79	Page 81
<p>1 term of this agreement."</p> <p>2 Did I read that correctly?</p> <p>3 A. Yes.</p> <p>4 Q. Turn back to the first page, top left. Does</p> <p>5 it read, "Joseph M. Carbone, M.D., Danville Urologic</p> <p>6 Clinic"?</p> <p>7 A. Yes.</p> <p>8 Q. You can put Exhibit 10 away.</p> <p>9 (Consulting Agreement, Joseph M. Carbone,</p> <p>10 M.D., January 5, 2006, ETH.MESH.00944191-00944198,</p> <p>11 marked for identification as Carbone Deposition Exhibit</p> <p>12 No. 11.)</p> <p>13 BY MR. JONES:</p> <p>14 Q. Exhibit 11 is dated January 5, 2006.</p> <p>15 Correct?</p> <p>16 A. Yes.</p> <p>17 Q. And you recognize this is as a contract</p> <p>18 between yourself and Ethicon?</p> <p>19 A. Yes.</p> <p>20 Q. Okay. I want to read the first sentence.</p> <p>21 "Ethicon is pleased that you have agreed to</p> <p>22 serve as a faculty member at training meetings</p> <p>23 conducted by the company for its sales force</p> <p>24 representatives."</p>	<p>1 BY MR. JONES:</p> <p>2 Q. In your role as a consultant for Ethicon, you</p> <p>3 helped train the Ethicon sales force at different</p> <p>4 times. Correct?</p> <p>5 A. Yes.</p> <p>6 Q. Skip down to paragraph 3.</p> <p>7 Ethicon would pay you \$375 per hour to help</p> <p>8 train its sales force in the year 2006. Correct?</p> <p>9 A. The hourly rate was \$375, but since these</p> <p>10 meetings were in New Jersey, it would usually be simply</p> <p>11 one day.</p> <p>12 Q. The hourly rate, as stated in the 2006</p> <p>13 contract that you signed with Ethicon, states that</p> <p>14 you'll be paid \$375 per hour to train their sales</p> <p>15 force. Correct?</p> <p>16 A. Yes.</p> <p>17 Q. And because many of these meetings where you</p> <p>18 trained Ethicon sales force occurred at the Ethicon</p> <p>19 headquarters, you were actually paid \$3,000 per day.</p> <p>20 Correct?</p> <p>21 A. Yes.</p> <p>22 Q. Skip to paragraph 5 on page 2. It would be</p> <p>23 two or three sentences down starting with "You agree."</p> <p>24 A. I'm sorry. What? Got it.</p>

21 (Pages 78 to 81)

Joseph M. Carbone, M.D.

Page 82	Page 84
<p>1 Q. "You agree that you shall not disclose the</p> <p>2 confidential information to any person unless you have</p> <p>3 received prior written authorization from the company."</p> <p>4 Did I read that correctly?</p> <p>5 A. Yes.</p> <p>6 Q. Was it your understanding that you were not</p> <p>7 to disclose confidential information you learned in</p> <p>8 your role as a consultant for Ethicon without getting</p> <p>9 prior written consent from Ethicon?</p> <p>10 A. I believe if I was in a litigation issue, I</p> <p>11 probably -- that was exempt, but, no, I'm not supposed</p> <p>12 to.</p> <p>13 Q. Put that one away. Keep going.</p> <p>14 THE DEPONENT: Is this 11?</p> <p>15 THE COURT REPORTER: Yes.</p> <p>16 THE DEPONENT: You have your copy?</p> <p>17 MR. JONES: Yeah. I've got my copy.</p> <p>18 THE DEPONENT: I just noticed it didn't have</p> <p>19 a number, and these have numbers.</p> <p>20 MR. JONES: I'm sorry.</p> <p>21 THE COURT REPORTER: That's okay.</p> <p>22 MR. JONES: We'll skip that one.</p> <p>23 Is it 12?</p> <p>24 (Consulting Agreement, Joseph M. Carbone,</p>	<p>1 Q. Okay. Put that one away.</p> <p>2 And Doctor, when we went through the Ethicon</p> <p>3 mesh products you used yesterday, we might have left</p> <p>4 one off. Gynemesh PS Flat Mesh, did you ever use that</p> <p>5 Ethicon product?</p> <p>6 A. I'm not aware. I may have when I was working</p> <p>7 at UCLA.</p> <p>8 Q. Okay.</p> <p>9 A. There was another product, too.</p> <p>10 Q. What is that?</p> <p>11 A. Prolene Suture.</p> <p>12 Q. Prolene Suture. Okay. That's not a mesh</p> <p>13 though. Right?</p> <p>14 A. I'm apologize. You asked -- thank you. I</p> <p>15 thought you had said --</p> <p>16 Q. Thanks.</p> <p>17 A. -- Ethicon products.</p> <p>18 Q. That brings up a big point.</p> <p>19 What are the differences between the Prolene</p> <p>20 suture and the Prolene mesh?</p> <p>21 A. One is woven and one is a suture. One is --</p> <p>22 Q. How many sutures, Prolene sutures make up a</p> <p>23 TVT Prolene mesh?</p> <p>24 MR. ROSENBLATT: Object to form.</p>
Page 83	Page 85
<p>1 M.D., January 11, 2011, ETH.MESH.05791448-05791457,</p> <p>2 marked for identification as Carbone Deposition Exhibit</p> <p>3 No. 12.)</p> <p>4 BY MR. JONES:</p> <p>5 Q. Doctor, do you recognize this as the</p> <p>6 consulting agreement you signed dated January of 2011?</p> <p>7 A. Yes.</p> <p>8 Q. This is the consulting agreement between</p> <p>9 yourself and Ethicon for 2011. Correct?</p> <p>10 A. Yes.</p> <p>11 Q. Turn to page -- it's paragraph 13, which</p> <p>12 would be page 3.</p> <p>13 A. Oh, I'm sorry. I'm looking...</p> <p>14 "You shall"... Okay.</p> <p>15 Q. I'm going to read that sentence.</p> <p>16 "You shall not make any representation</p> <p>17 relating to company's products or to company's clinical</p> <p>18 outcomes unless such representations have been reviewed</p> <p>19 in advance by the company."</p> <p>20 Did I read that correctly?</p> <p>21 A. Yes, sir.</p> <p>22 Q. Is that a term you agreed to when you signed</p> <p>23 this contract in 2011?</p> <p>24 A. Yes, sir.</p>	<p>1 THE DEPONENT: I don't know.</p> <p>2 BY MR. JONES:</p> <p>3 Q. You don't know?</p> <p>4 A. No.</p> <p>5 Q. You don't know how much mass it takes of</p> <p>6 Prolene sutures to make up a TVT Retropubic mesh?</p> <p>7 A. I know it's a standard size, 1.1 centimeters</p> <p>8 wide, standard length, but I don't know how many</p> <p>9 sutures are involved in that product.</p> <p>10 Q. Mesh is a much -- mesh contains more Prolene</p> <p>11 material than a suture. Fair?</p> <p>12 A. Depends on how long the suture is, but fair</p> <p>13 to say, yes.</p> <p>14 Q. Okay. You've seen a suture that's long</p> <p>15 enough that contains more Prolene material than</p> <p>16 TVT Retropubic mesh?</p> <p>17 A. I've not seen one.</p> <p>18 Q. Okay. Didn't think so.</p> <p>19 We went through some of the cities yesterday</p> <p>20 that Ethicon's paid for you to travel to in your role</p> <p>21 as a consultant, and I want to go back to some of</p> <p>22 those.</p> <p>23 We already agreed Miami was one of those</p> <p>24 cities. Correct?</p>

22 (Pages 82 to 85)

Joseph M. Carbone, M.D.

Page 86	Page 88
<p>1 MR. ROSENBLATT: Asked and answered.</p> <p>2 THE DEPONENT: Yes.</p> <p>3 BY MR. JONES:</p> <p>4 Q. We already agreed Napa Valley was one of</p> <p>5 those places. Correct?</p> <p>6 MR. ROSENBLATT: Asked and answered.</p> <p>7 THE DEPONENT: Yes.</p> <p>8 BY MR. JONES:</p> <p>9 Q. Scottsdale, Arizona?</p> <p>10 MR. ROSENBLATT: Asked and answered.</p> <p>11 MR. JONES: Has not been.</p> <p>12 THE DEPONENT: I don't remember.</p> <p>13 BY MR. JONES:</p> <p>14 Q. Don't remember. Okay.</p> <p>15 What exhibit number are we on?</p> <p>16 A. We are on No. 13.</p> <p>17 MR. JONES: 13.</p> <p>18 MR. FAES: Sorry.</p> <p>19 THE DEPONENT: I'm trying to be expeditious.</p> <p>20 MR. JONES: You are. You're helpful. I</p> <p>21 appreciate it.</p> <p>22 (Various e-mails, Re: Outstanding Payments,</p> <p>23 EH.MESH.19258345-19258347, marked for identification as</p> <p>24 Carbone Deposition Exhibit No. 13.)</p>	<p>1 A. I believe so, yes.</p> <p>2 Q. Okay. Is the subject line "Outstanding</p> <p>3 payments"?</p> <p>4 A. Yes, sir.</p> <p>5 Q. Okay. I'm going to skip to -- I'll read it</p> <p>6 in whole.</p> <p>7 "Erica, I was just reviewing my travel files</p> <p>8 and found three items that I have not been reimbursed."</p> <p>9 Did I read that correctly?</p> <p>10 A. I did not have "I" in there, "I have not been</p> <p>11 reimbursed."</p> <p>12 Q. Okay. Thanks.</p> <p>13 "First, I did a grand rounds lecture on</p> <p>14 Monday, March 22, at the Fairfax Inova Hospital. I</p> <p>15 received my expense check already, but I haven't</p> <p>16 received an Attachment A for my \$3,000 honorarium check</p> <p>17 for that lecture."</p> <p>18 Did I read that correctly, but for the</p> <p>19 parenthetical number?</p> <p>20 A. Yes.</p> <p>21 Q. Okay. Does this represent that you're</p> <p>22 contacting Ethicon in 2014 to get your \$3,000</p> <p>23 honorarium check for that lecture?</p> <p>24 A. It was 2004.</p>
Page 87	Page 89
<p>1 BY MR. JONES:</p> <p>2 Q. All right. Does this help refresh your</p> <p>3 recollection as to whether Ethicon paid for you to go</p> <p>4 to Scottsdale or not?</p> <p>5 The last page.</p> <p>6 A. Oh, the last page. I'm sorry.</p> <p>7 Q. Sorry, sorry, sorry.</p> <p>8 Here, I will give you my copy.</p> <p>9 A. (Deponent reading to himself.)</p> <p>10 Q. Go ahead and read the highlighted portion</p> <p>11 into the record.</p> <p>12 MR. ROSENBLATT: Is that a question?</p> <p>13 BY MR. JONES:</p> <p>14 Q. Go ahead and read the highlighted portion</p> <p>15 into the record, Dr. Carbone.</p> <p>16 MR. ROSENBLATT: Is that a question?</p> <p>17 THE DEPONENT: I'm going to have to have you</p> <p>18 read it.</p> <p>19 Can I borrow that?</p> <p>20 BY MR. JONES:</p> <p>21 Q. All right. Here we go, Doctor. Speed this</p> <p>22 up. I'll read, starting on page 3.</p> <p>23 First off, is this an e-mail you sent to</p> <p>24 Ethicon in 2004, Doctor?</p>	<p>1 Q. Okay. 2004 you contacted Ethicon for a</p> <p>2 \$3,000 honorarium check for a lecture. Correct?</p> <p>3 A. Yes.</p> <p>4 Q. Okay. Second paragraph, "I participated in</p> <p>5 the TVT-O telesurgery program in Miami, Florida, on</p> <p>6 March 23."</p> <p>7 Did I read that correctly?</p> <p>8 A. Yes.</p> <p>9 Q. "I'll resend the Attachment A's for both the</p> <p>10 honorarium and the expenses."</p> <p>11 Did I read that correctly?</p> <p>12 A. You skipped the intervening.</p> <p>13 Q. I did skip a sentence.</p> <p>14 How about this: Are you contacting Ethicon</p> <p>15 in 2004 in regards to a telesurgery program in Miami,</p> <p>16 Florida, for TVT-O in which you were wanting your</p> <p>17 honorarium and your expenses paid for?</p> <p>18 A. Yeah.</p> <p>19 Q. Okay. In the last paragraph it's discussing</p> <p>20 a MoniTorr conference in Scottsdale, Arizona. Correct?</p> <p>21 A. Yes.</p> <p>22 Q. And you're contacting Ethicon because you</p> <p>23 want a thousand dollar honorarium for your</p> <p>24 participation in a MoniTorr conference in Scottsdale,</p>

23 (Pages 86 to 89)

Joseph M. Carbone, M.D.

Page 90	Page 92
<p>1 Arizona, in 2004. Correct?</p> <p>2 A. Yes.</p> <p>3 Q. So we can add Scottsdale to the list of</p> <p>4 cities that Ethicon has paid you to travel to.</p> <p>5 Correct?</p> <p>6 A. You can add Scottsdale. Correct.</p> <p>7 Q. Can we add Birmingham, Alabama?</p> <p>8 A. Yes.</p> <p>9 Q. San Francisco?</p> <p>10 A. I don't remember.</p> <p>11 Q. Philadelphia?</p> <p>12 A. I don't remember.</p> <p>13 Q. Pittsburgh?</p> <p>14 A. I don't remember.</p> <p>15 Q. How about a trip to Williamsburg, Virginia,</p> <p>16 where there was a dinner and presentation on TVT and</p> <p>17 TVT-O in 2005 at the Kingsmill Resort?</p> <p>18 A. Yes.</p> <p>19 Q. Okay. What was the Kingsmill Resort like?</p> <p>20 A. It's nice enough.</p> <p>21 Q. It was nice. Nice.</p> <p>22 Okay. On these events that you went to, were</p> <p>23 there often dinners that you attended --</p> <p>24 A. Yes.</p>	<p>1 A. I don't remember that one.</p> <p>2 Q. Don't remember that one?</p> <p>3 A. No.</p> <p>4 Q. We talked a little bit about the first sales</p> <p>5 rep you ever -- you had when you came to Danville.</p> <p>6 Were you ever made aware that she was awarded two Rolex</p> <p>7 watches for the amount of sales she achieved in your</p> <p>8 region?</p> <p>9 MR. ROSENBLATT: Objection. Lack of</p> <p>10 foundation.</p> <p>11 THE DEPONENT: No.</p> <p>12 BY MR. JONES:</p> <p>13 Q. Were you ever a faculty member in a</p> <p>14 preceptorship or cadaver where you taught others about</p> <p>15 complications of Prolift mesh?</p> <p>16 A. Yes.</p> <p>17 Q. Were you ever involved in a preceptorship or</p> <p>18 cadaver lab where you taught surgeons about</p> <p>19 complications associated with TVT mesh?</p> <p>20 A. I taught about complications from the TVT</p> <p>21 procedures.</p> <p>22 Q. Have you served on advisory boards for</p> <p>23 Ethicon?</p> <p>24 A. I don't recall specifically.</p>
Page 91	Page 93
<p>1 Q. -- with Ethicon employees?</p> <p>2 A. Yes.</p> <p>3 Q. Who paid for those dinners?</p> <p>4 A. I don't know who wrote the check.</p> <p>5 Q. Did you ever pay for those dinners?</p> <p>6 A. No.</p> <p>7 Q. How about Baltimore?</p> <p>8 A. Yes.</p> <p>9 Q. Dallas at the Hotel ZaZa in 2010, TVT Exact?</p> <p>10 A. I don't remember the Hotel ZaZa.</p> <p>11 Q. Do you remember Dallas, traveling to Dallas</p> <p>12 for TVT Exact in 2010 for Ethicon?</p> <p>13 A. I don't remember.</p> <p>14 Q. Do you recall a TVT Exact lab in Phoenix</p> <p>15 where you stayed at the JW Marriott in 2010?</p> <p>16 A. No.</p> <p>17 Q. Nashville?</p> <p>18 A. No.</p> <p>19 Q. You don't recall Nashville?</p> <p>20 A. I don't recall.</p> <p>21 Q. Chicago, where you ate at Gibsons Steakhouse</p> <p>22 and stayed at the Hyatt n 2011?</p> <p>23 A. I don't recall.</p> <p>24 Q. Chesapeake Bay, 2011, Prosima, proctor?</p>	<p>1 Q. Have you ever participated in what Ethicon</p> <p>2 refers to as innovation councils?</p> <p>3 A. I don't recall specifically.</p> <p>4 MR. JONES: What exhibit are we on?</p> <p>5 THE DEPONENT: 13. No, no, no. Wait. 14.</p> <p>6 MR. JONES: Thanks, Doctor.</p> <p>7 (July Highlights, YTD of Professional</p> <p>8 Education Events, ETH.MESH.05794991-05794992, marked</p> <p>9 for identification as Carbone Deposition Exhibit</p> <p>10 No. 14.)</p> <p>11 BY MR. JONES:</p> <p>12 Q. There you go. Sorry.</p> <p>13 I'm just going to read the highlighted</p> <p>14 portion --</p> <p>15 A. Okay.</p> <p>16 Q. -- so if you want to focus on that.</p> <p>17 A. Got it.</p> <p>18 Q. All right. Cool.</p> <p>19 This is titled "July Highlights, Year-to-Date</p> <p>20 of Professional Education Events." Correct?</p> <p>21 A. Yes.</p> <p>22 Q. Look right there, there's a date of</p> <p>23 2004 July. Correct?</p> <p>24 A. Yes.</p>

24 (Pages 90 to 93)

Joseph M. Carbone, M.D.

Page 94	Page 96
<p>1 Q. Okay. On this document. Correct?</p> <p>2 A. Yes.</p> <p>3 Q. Under the heading Gynecare MoniTorr, it</p> <p>4 states -- okay, are you with me?</p> <p>5 A. Yes.</p> <p>6 Q. Okay. You conducted two events for Ethicon</p> <p>7 related to MoniTorr. Correct?</p> <p>8 A. "Two of these events were conducted by Joseph</p> <p>9 Carbone."</p> <p>10 Yes.</p> <p>11 Q. Okay. Those two events conducted by you on</p> <p>12 MoniTorr resulted in the sale of two MoniTorr units.</p> <p>13 Correct?</p> <p>14 A. I wasn't aware of that, but yes.</p> <p>15 Q. Okay. Are there -- was it customary for</p> <p>16 doctors to purchase Ethicon products after they</p> <p>17 attended Ethicon professional education events that you</p> <p>18 conducted?</p> <p>19 A. I don't know.</p> <p>20 Q. Would you describe yourself as a good</p> <p>21 customer of Ethicon?</p> <p>22 MR. ROSENBLATT: Object to form.</p> <p>23 THE DEPONENT: I don't know what "good" is.</p> <p>24 I mean, I don't know how you would scale good.</p>	<p>1 Q. You wouldn't describe yourself as a loyal</p> <p>2 customer of Ethicon mesh products in your career here</p> <p>3 in Danville, Virginia?</p> <p>4 MR. ROSENBLATT: Object to form. Asked and</p> <p>5 answered twice.</p> <p>6 MR. JONES: No. No.</p> <p>7 THE DEPONENT: I was loyal to the procedures.</p> <p>8 I was loyal to the technique and the mesh that had the</p> <p>9 highest clinical data, the most -- and the most -- and</p> <p>10 the highest Level 1 data for my patients, that had the</p> <p>11 highest cure rate and safety for my patients.</p> <p>12 BY MR. JONES:</p> <p>13 Q. And you currently use TVT Exact on your</p> <p>14 patients. Correct?</p> <p>15 A. Yes.</p> <p>16 Q. Would you describe yourself as a partner with</p> <p>17 Ethicon over the course of your medical career here in</p> <p>18 Danville?</p> <p>19 MR. ROSENBLATT: Object to form.</p> <p>20 THE DEPONENT: No.</p> <p>21 BY MR. JONES:</p> <p>22 Q. Would you be surprised if Ethicon ever</p> <p>23 described you as a partner?</p> <p>24 A. I would be disappointed if they did.</p>
Page 95	Page 97
<p>1 BY MR. JONES:</p> <p>2 Q. Would you describe yourself as a loyal</p> <p>3 customer of Ethicon?</p> <p>4 MR. ROSENBLATT: Object to form.</p> <p>5 THE DEPONENT: I felt the TVT products and</p> <p>6 the Prolift had the best Level 1 evidence with respect</p> <p>7 to safety and efficacy. So in that regard, I used</p> <p>8 those products.</p> <p>9 BY MR. JONES:</p> <p>10 Q. Yes or no, would you consider yourself a</p> <p>11 loyal customer of Ethicon dating back to your first use</p> <p>12 of Ethicon mesh products in -- in the early 2000s?</p> <p>13 MR. ROSENBLATT: Object to form. I think he</p> <p>14 just answered.</p> <p>15 MR. JONES: He didn't.</p> <p>16 THE DEPONENT: In the early 2000s, like when</p> <p>17 I was working with Dr. Raz.</p> <p>18 BY MR. JONES:</p> <p>19 Q. When you came to Danville.</p> <p>20 A. Oh, okay.</p> <p>21 Q. How about that?</p> <p>22 A. Okay. I'm with you.</p> <p>23 Q. I appreciate it.</p> <p>24 A. Not Ethicon.</p>	<p>1 Q. Would you be surprised if they ever described</p> <p>2 you as a loyal customer of theirs?</p> <p>3 A. I would be disappointed if they did.</p> <p>4 Q. Are you aware that you have implanted more</p> <p>5 TVT products than any other doctor in the state of</p> <p>6 Virginia?</p> <p>7 A. I'm sorry?</p> <p>8 Q. Are you aware that you've implanted more TVT</p> <p>9 products than any other doctor in the state of</p> <p>10 Virginia?</p> <p>11 MR. ROSENBLATT: Object to form. Lack of</p> <p>12 foundation.</p> <p>13 THE DEPONENT: No.</p> <p>14 BY MR. JONES:</p> <p>15 Q. Would it surprise you if you had used more</p> <p>16 TVT products than any other doctor in Southern</p> <p>17 Virginia?</p> <p>18 MR. ROSENBLATT: Object to form.</p> <p>19 THE DEPONENT: As the only female pelvic --</p> <p>20 female pelvic medicine and reconstructive surgeon in</p> <p>21 Southern Virginia, it would not surprise me that I've</p> <p>22 done more pelvic floor repairs and incontinence</p> <p>23 procedures than any other surgeon in the -- in the area</p> <p>24 of Southern Virginia, so...</p>

25 (Pages 94 to 97)

Joseph M. Carbone, M.D.

Page 98	Page 100
<p>1 BY MR. JONES:</p> <p>2 Q. Fair. Let me expand it, then --</p> <p>3 A. All right.</p> <p>4 Q. -- to Virginia, the state of Virginia.</p> <p>5 Would it surprise you if you've implanted</p> <p>6 more TVT products than any other doctor in the entire</p> <p>7 state of Virginia?</p> <p>8 MR. ROSENBLATT: Object to form. Lack of</p> <p>9 foundation.</p> <p>10 THE DEPONENT: Yes.</p> <p>11 BY MR. JONES:</p> <p>12 Q. Would it surprise you if Ethicon described</p> <p>13 you as one of the top ten users of TVT mesh products in</p> <p>14 the entire country?</p> <p>15 A. I would be disappointed if Ethicon did that.</p> <p>16 MR. JONES: Let's go off the record real</p> <p>17 quick.</p> <p>18 (Whereupon, a recess was taken from 7:50 p.m.</p> <p>19 to 7:55 p.m.)</p> <p>20 BY MR. JONES:</p> <p>21 Q. Ready, Doctor, to proceed after a very short</p> <p>22 break?</p> <p>23 A. Yes, sir.</p> <p>24 Q. Are you aware that Dennis Miller has invented</p>	<p>1 Q. Okay. Does the inventor of a product have</p> <p>2 bias towards the use of the product they invented?</p> <p>3 MR. ROSENBLATT: Object to form.</p> <p>4 THE DEPONENT: I don't know.</p> <p>5 BY MR. JONES:</p> <p>6 Q. You don't know. Does -- is Ulf Ulmsten</p> <p>7 biased towards TVT when he was alive?</p> <p>8 MR. ROSENBLATT: Object to form.</p> <p>9 THE DEPONENT: I don't know.</p> <p>10 BY MR. JONES:</p> <p>11 Q. You don't know?</p> <p>12 A. No.</p> <p>13 Q. Is an inventor biased toward their own</p> <p>14 product?</p> <p>15 MR. ROSENBLATT: Object to form.</p> <p>16 THE DEPONENT: I don't know.</p> <p>17 BY MR. JONES:</p> <p>18 Q. Don't know.</p> <p>19 Should an inventor disclose in medical</p> <p>20 literature their potential conflict of interest related</p> <p>21 to them inventing the product they're reporting on?</p> <p>22 MR. ROSENBLATT: Object to form.</p> <p>23 THE DEPONENT: What period of time are you</p> <p>24 stating?</p>
Page 99	Page 101
<p>1 a mesh product?</p> <p>2 A. No.</p> <p>3 Q. Are you aware that complications related to</p> <p>4 transvaginal mesh are underreported?</p> <p>5 MR. ROSENBLATT: Object to form.</p> <p>6 THE DEPONENT: What transvaginal mesh are you</p> <p>7 talking about?</p> <p>8 BY MR. JONES:</p> <p>9 Q. Are you aware that TVT complications are</p> <p>10 underreported?</p> <p>11 MR. ROSENBLATT: Object to form.</p> <p>12 BY MR. JONES:</p> <p>13 Q. I don't have that much time. You don't have</p> <p>14 an answer?</p> <p>15 A. I'm not aware.</p> <p>16 Q. Do you -- do you know that not every TVT mesh</p> <p>17 complication gets reported to Ethicon?</p> <p>18 MR. ROSENBLATT: Object to form.</p> <p>19 THE DEPONENT: Not every TVT mesh</p> <p>20 complication gets reported to Ethicon?</p> <p>21 BY MR. JONES:</p> <p>22 Q. Right.</p> <p>23 A. Gets reported to Ethicon? Sure.</p> <p>24 Underreported? Don't know.</p>	<p>1 BY MR. JONES:</p> <p>2 Q. All periods.</p> <p>3 A. I mean, should an inventor -- I'm sorry. Go</p> <p>4 ahead. Restate the question. I apologize.</p> <p>5 Q. We'll move on.</p> <p>6 A. Okay.</p> <p>7 Q. We'll move on. I don't have much time.</p> <p>8 A. Okay.</p> <p>9 MR. JONES: All right. Exhibit 19, or</p> <p>10 whatever exhibit we're on.</p> <p>11 MR. ROSENBLATT: 15.</p> <p>12 (Various e-mails, Re: GYNECARE Prof. Ed -</p> <p>13 Teaching Engagement Confirmation, ETH.MESH.11842773 &</p> <p>14 11842774, marked for identification as Carbone</p> <p>15 Deposition Exhibit No. 15.)</p> <p>16 BY MR. JONES:</p> <p>17 Q. Here's the highlighted portion. I'm going to</p> <p>18 read that.</p> <p>19 Is this a 2007 e-mail, Dr. Carbone?</p> <p>20 A. Yes.</p> <p>21 Q. Okay. Do you recognize your name and e-mail</p> <p>22 address on this first page in the middle of the page?</p> <p>23 A. Yes.</p> <p>24 Q. Okay. Did you write this e-mail in 2007 from</p>

26 (Pages 98 to 101)

Golkow Technologies, Inc. - 1.877.370.DEPS

Joseph M. Carbone, M.D.

Page 102	Page 104
<p>1 your e-mail address? Did you send this e-mail in 2007?</p> <p>2 A. Yes, yes, yes. Sure.</p> <p>3 Q. Okay. I'm going to read the highlighted</p> <p>4 portion.</p> <p>5 Do you know who Joseph Steele at Ethicon is?</p> <p>6 A. Honestly, I don't remember.</p> <p>7 Q. Okay. And he's writing about you,</p> <p>8 Dr. Carbone, correct, in 2007? Correct?</p> <p>9 A. Yes.</p> <p>10 Q. And he says, "Thank you for thinking of us</p> <p>11 and being such a good partner and customer."</p> <p>12 Did I read that correctly?</p> <p>13 A. Yes.</p> <p>14 Q. "Joseph A. Steel, Division Manager, New</p> <p>15 England Division." Correct?</p> <p>16 A. Yeah.</p> <p>17 Q. And he wrote that to you, Dr. Carbone.</p> <p>18 Correct?</p> <p>19 A. Yes.</p> <p>20 Q. Okay. Do you think you were a good partner</p> <p>21 and customer for Ethicon?</p> <p>22 A. No.</p> <p>23 Q. So you disagree with what he wrote there?</p> <p>24 A. Yes.</p>	<p>1 A. Yes.</p> <p>2 MR. JONES: Okay. We're going to the next</p> <p>3 one.</p> <p>4 THE DEPONENT: Oh, okay.</p> <p>5 MR. JONES: Okay. Exhibit 17.</p> <p>6 (Operation Abbrevio Combat Training Splash</p> <p>7 Storyboard, ETH.MESH.09170211-09170213, marked for</p> <p>8 identification as Carbone Deposition Exhibit No. 17.)</p> <p>9 BY MR. JONES:</p> <p>10 Q. The title of this is "Operation Abbrevio</p> <p>11 Combat Slash Storyboard." Correct?</p> <p>12 MR. ROSENBLATT: Nate, I want to stop you</p> <p>13 real quick. I want to make sure if you plan to do a</p> <p>14 redirect, that you save yourself a little time.</p> <p>15 MR. JONES: No. I'm going to base it upon</p> <p>16 the time that you spend, so I don't know what time I'm</p> <p>17 going to have to do. That's the whole point of</p> <p>18 redirect, Paul. I have got time for it.</p> <p>19 MR. ROSENBLATT: I know, but you need to save</p> <p>20 yourself some time.</p> <p>21 MR. JONES: I've got time for it.</p> <p>22 Same thing we did last week with your expert,</p> <p>23 Paul. I don't know why you're being so difficult about</p> <p>24 this.</p>
Page 103	Page 105
<p>1 Q. Okay. Go to the next exhibit.</p> <p>2 MR. ROSENBLATT: Do you want to keep this</p> <p>3 as -- the exhibit was 15, but you said 19.</p> <p>4 MR. JONES: Okay. We'll make it the next</p> <p>5 exhibit, 15 then.</p> <p>6 This will be 16.</p> <p>7 (American Urological Association Annual</p> <p>8 Meeting Advertising Card, ETH.MESH.05793768 & 05793769,</p> <p>9 marked for identification as Carbone Deposition Exhibit</p> <p>10 No. 16.)</p> <p>11 THE DEPONENT: Do you want to switch this</p> <p>12 to 15?</p> <p>13 MR. JONES: Yes. Thanks.</p> <p>14 THE DEPONENT: No problem.</p> <p>15 BY MR. JONES:</p> <p>16 Q. All right. Exhibit 16. Second page.</p> <p>17 A. Second page.</p> <p>18 Q. The bottom of the second page, focus on the</p> <p>19 highlighted portions.</p> <p>20 Does this appear that you, Dr. Carbone, were</p> <p>21 in a Gynecare booth at the 2004 AUA annual meeting?</p> <p>22 A. Yeah.</p> <p>23 Q. So in 2004 you served in a booth for Ethicon</p> <p>24 at the AUA national convention. Correct?</p>	<p>1 MR. ROSENBLATT: I don't know what you're</p> <p>2 talking about, so...</p> <p>3 MR. JONES: I'll get that record from you, if</p> <p>4 that will help you.</p> <p>5 MR. ROSENBLATT: No --</p> <p>6 MR. JONES: Now you're taking up more of my</p> <p>7 time, so stop.</p> <p>8 MR. ROSENBLATT: I'll give you an extra</p> <p>9 minute.</p> <p>10 BY MR. JONES:</p> <p>11 Q. All right. Dr. Carbone --</p> <p>12 A. Yes, sir.</p> <p>13 Q. Do you recognize this?</p> <p>14 A. No.</p> <p>15 Q. You don't remember participating an Abbrevio</p> <p>16 military-style video?</p> <p>17 A. No.</p> <p>18 Q. No? Okay. If we had more time, I'd play it</p> <p>19 for you, but we don't.</p> <p>20 A. Okay.</p> <p>21 Q. We'll do it after, maybe.</p> <p>22 All right. Turn to the second page.</p> <p>23 Dr. Grier -- do you know who Dr. Grier is?</p> <p>24 Dr. Doug Grier, do you know him?</p>

27 (Pages 102 to 105)

Joseph M. Carbone, M.D.

Page 106	Page 108
<p>1 A. I remember the name, but I don't remember</p> <p>2 him.</p> <p>3 Q. Okay. You see your name, Dr. Carbone, at the</p> <p>4 bottom of page 2?</p> <p>5 A. Yes, I do.</p> <p>6 Q. Does this refresh your recollection at all</p> <p>7 that you participated in the video?</p> <p>8 A. No.</p> <p>9 Q. Okay. Dr. Grier says, "I think Abbrevio is a</p> <p>10 superior product because it doesn't require a new skill</p> <p>11 set. It's easier to adjust and hopefully it will bear</p> <p>12 out that there is less pain involved when it comes to</p> <p>13 postoperative care."</p> <p>14 Do you agree or disagree with that statement?</p> <p>15 A. Do you mean do I agree that that was the</p> <p>16 statement?</p> <p>17 Q. No. Do you agree --</p> <p>18 A. Okay. I'm sorry.</p> <p>19 Q. -- or disagree --</p> <p>20 A. With the content.</p> <p>21 Q. -- with the content of that statement?</p> <p>22 A. (The deponent reads to himself.)</p> <p>23 Superior to what? It's very unclear.</p> <p>24 Q. T-V-T-O.</p>	<p>1 A. It's a no.</p> <p>2 Q. Thanks.</p> <p>3 A. All right.</p> <p>4 Q. Trust me, it's a lot better on the record if</p> <p>5 you answer the questions.</p> <p>6 Dr. Erikson, do you know who Dr. Erikson is?</p> <p>7 A. Yes, I do, Debbie Erikson.</p> <p>8 Q. And I take it you know him from your time</p> <p>9 as --</p> <p>10 A. Do I know him?</p> <p>11 Q. -- as a consultant?</p> <p>12 Him. Ty Erikson.</p> <p>13 A. I got --</p> <p>14 Q. Dr. Ty Erikson.</p> <p>15 A. I got the wrong --</p> <p>16 Q. You don't know Dr. Ty Erikson in Idaho?</p> <p>17 A. I apologize.</p> <p>18 Q. Okay. He states, "Many slings require a</p> <p>19 higher skill set to make sure you're reproducing its</p> <p>20 application. So in training I think the Abbrevio, when</p> <p>21 you spread it out to the larger mass of surgeons, will</p> <p>22 have a more reproducible result than mini slings."</p> <p>23 Do you agree or disagree with the content of</p> <p>24 that statement?</p>
Page 107	Page 109
<p>1 MR. ROSENBLATT: Object to form.</p> <p>2 THE DEPONENT: I don't like the statement at</p> <p>3 all.</p> <p>4 BY MR. JONES:</p> <p>5 Q. Do you disagree or agree?</p> <p>6 A. There's a lot that I disagree with.</p> <p>7 Q. Okay. Thank you.</p> <p>8 Do you think the T-V-T Abbrevio is a superior</p> <p>9 product to T-V-T-O, yes or no?</p> <p>10 MR. ROSENBLATT: Object to form.</p> <p>11 THE DEPONENT: I think it's equivalent.</p> <p>12 BY MR. JONES:</p> <p>13 Q. Do you think it's superior, yes or no?</p> <p>14 MR. ROSENBLATT: Object to form. Asked and</p> <p>15 answered.</p> <p>16 MR. JONES: He didn't answer it.</p> <p>17 THE DEPONENT: I think it's equivalent.</p> <p>18 BY MR. JONES:</p> <p>19 Q. So that's a no?</p> <p>20 A. That's a no.</p> <p>21 Q. If it's equivalent -- okay. That's what</p> <p>22 I'm --</p> <p>23 A. Okay. I'm with you.</p> <p>24 Q. -- giving you, yes-or-no questions, Doctor.</p>	<p>1 A. I disagree with it.</p> <p>2 MR. JONES: Okay. I think that's all the</p> <p>3 questions I have, Doctor. Okay.</p> <p>4</p> <p>5 EXAMINATION</p> <p>6 BY MR. ROSENBLATT:</p> <p>7 Q. All right. Doctor, my name is Paul</p> <p>8 Rosenblatt. I represent Ethicon. I'm going to ask you</p> <p>9 a few questions to follow up after your general</p> <p>10 depositions on Prolift, T-V-T and T-V-T-O. Okay?</p> <p>11 A. Okay.</p> <p>12 Q. Now, I understand you brought with you a</p> <p>13 number of materials. Is that correct?</p> <p>14 A. Yes.</p> <p>15 Q. And those would be the three bankers boxes of</p> <p>16 documents that have been printed out in the binders</p> <p>17 behind us?</p> <p>18 A. Yes.</p> <p>19 Q. And are those materials that you would have</p> <p>20 reviewed in this case?</p> <p>21 A. Yes.</p> <p>22 Q. Okay. Doctor, in your practice have you gone</p> <p>23 back and done any type of systematic review of your</p> <p>24 complications?</p>

28 (Pages 106 to 109)

Joseph M. Carbone, M.D.

Page 110	Page 112
<p>1 A. I've asked my office manager to look up the</p> <p>2 ICD-9 codes for erosion of the mesh for the vagina, and</p> <p>3 she was able to provide for me several years of</p> <p>4 ICD-9 -- well, ICD-9 and ICD-10 codes now, and that's</p> <p>5 how I was able to come up with the number of</p> <p>6 complications that I quoted.</p> <p>7 Q. And based on these complication codes or CPT</p> <p>8 or -- what was the --</p> <p>9 A. ICD-9 and ICD-10 coding.</p> <p>10 Q. Based on that coding, what were you able to</p> <p>11 determine, based on the data available, was your</p> <p>12 complication rate for mesh erosions?</p> <p>13 A. I would say my complication rate was a little</p> <p>14 lower than the reported complication rate in the</p> <p>15 medical literature, the randomize control trial, the</p> <p>16 analysis.</p> <p>17 Q. And would be this be for the TVT products?</p> <p>18 A. For the TVT products and also for some of the</p> <p>19 Prolene -- sorry, the Prolift product and Prosima.</p> <p>20 Q. Okay.</p> <p>21 A. I should say prolapse products. I put them</p> <p>22 all together.</p> <p>23 Q. Now, would you agree that the erosion rates</p> <p>24 that you just told us, are a little bit lower than some</p>	<p>1 BY MR. ROSENBLATT:</p> <p>2 Q. And would you say in a rural area such as</p> <p>3 Southern Virginia, that your follow-up with patients is</p> <p>4 pretty high?</p> <p>5 MR. JONES: Objection.</p> <p>6 THE DEPONENT: I believe my follow-up with</p> <p>7 patients is pretty high.</p> <p>8 BY MR. ROSENBLATT:</p> <p>9 Q. Now, Doctor, have you reviewed the</p> <p>10 literature, the randomized control trials, evaluating</p> <p>11 Prolift and other vaginal mesh kits compared to native</p> <p>12 tissue repairs for pelvic organ prolapse?</p> <p>13 A. I have.</p> <p>14 Q. And when you reviewed those randomized</p> <p>15 control trials, did they show any difference between</p> <p>16 rates of vaginal or pelvic pain or de novo dyspareunia?</p> <p>17 MR. JONES: Objection.</p> <p>18 THE DEPONENT: No significant differences.</p> <p>19 BY MR. ROSENBLATT:</p> <p>20 Q. So, Doctor, when counsel was asking you</p> <p>21 questions about does the product cause pain, would you</p> <p>22 like to explain some of the answers that you were</p> <p>23 trying to give there?</p> <p>24 MR. JONES: Objection.</p>
Page 111	Page 113
<p>1 of the averages we've seen in the medical literature?</p> <p>2 A. Yes.</p> <p>3 Q. To the best of your understanding, why do you</p> <p>4 think that might be?</p> <p>5 A. Well, to the best of my understanding, I feel</p> <p>6 like my patient population is a unique patient</p> <p>7 population in that I get the first swing at things.</p> <p>8 They are a patient population that had not</p> <p>9 been operated on before, typically, with respect to</p> <p>10 urinary incontinence and pelvic floor prolapse. So I'm</p> <p>11 not dealing with re-operations, and I'm able to provide</p> <p>12 the first and best operation for the patient for their</p> <p>13 urinary incontinence and pelvis floor prolapse.</p> <p>14 Q. And, Doctor, I think you mentioned to</p> <p>15 Mr. Jones that you were one of the only, if not the</p> <p>16 only, subspecialty female pelvic medicine</p> <p>17 reconstructive surgery -- surgeons in the -- was it the</p> <p>18 Southern Virginia area?</p> <p>19 MR. JONES: I will object to form.</p> <p>20 THE DEPONENT: Yes. To the best of my</p> <p>21 understanding, I'm the only female pelvic medicine</p> <p>22 reconstructive surgeon from about Suffolk to the Blue</p> <p>23 Ridge Mountains.</p> <p>24</p>	<p>1 THE DEPONENT: When he asked me that</p> <p>2 question, I said I don't attribute it to the product.</p> <p>3 I attribute it to the pelvic surgery, and any pelvic</p> <p>4 surgery for the treatment of prolapse is associated</p> <p>5 with complications. The unique complication associated</p> <p>6 with the use of mesh products, specifically the Prolift</p> <p>7 product, is erosion of the mesh.</p> <p>8 Now, if you're talking about pain, if you're</p> <p>9 talking about dyspareunia, de novo dyspareunia, I don't</p> <p>10 attribute that specifically to the product. I</p> <p>11 attribute that to the pelvic surgery.</p> <p>12 BY MR. ROSENBLATT:</p> <p>13 Q. And is it fair to say that the pain or</p> <p>14 dyspareunia is a well-known complication by surgeons in</p> <p>15 their field for any pelvic floor surgery?</p> <p>16 MR. JONES: Objection.</p> <p>17 THE DEPONENT: It is a well-known</p> <p>18 complication of surgeons in my field of any pelvic</p> <p>19 floor surgery.</p> <p>20 BY MR. ROSENBLATT:</p> <p>21 Q. And, Doctor, you're offering opinions about</p> <p>22 the adequacy of the warnings in the Prolift, TVT, and</p> <p>23 TVT-O instructions for use. Correct?</p> <p>24 A. Yes, I am.</p>

29 (Pages 110 to 113)

Joseph M. Carbone, M.D.

Page 114	Page 116
<p>1 Q. And what are your opinions regarding the IFUs 2 for Prolift, TVT, and TVT-O? 3 A. I believe they adequately restricted the 4 unique complications associated with those products. 5 Q. And -- 6 MR. JONES: These questions were asked 7 already, but go ahead. 8 BY MR. ROSENBLATT: 9 Q. What are you -- how do you know what -- 10 strike that. 11 What are you basing your opinions on that the 12 IFUs are adequate? 13 MR. JONES: Objection. 14 THE DEPONENT: I have -- first and foremost, 15 I have my education and my training. I have my 16 experience, but more than that, you can look at a 17 number of different reports in the medical literature 18 regarding randomized control trials using these 19 products, and the safety and efficacy regarding those 20 products, and the statements also of the main 21 societies, including the AUA, OGS, SUFU, as well as the 22 general knowledge that pelvic floor surgeons have 23 regarding pelvic floor surgery. 24</p>	<p>1 IFUs. We have our knowledge. And again, we have the 2 knowledge, the training, we have the knowledge from our 3 training, we the knowledge from our experience, but in 4 addition, we refer to the medical literature to 5 maintain our certification, to maintain our 6 understanding, and to keep abreast of the field. 7 You know, it's not -- that's where we get our 8 knowledge regarding the complications associated with 9 the pelvic floor surgery. 10 BY MR. ROSENBLATT: 11 Q. Now, when you say medical literature is where 12 surgeons get their knowledge regarding complications, 13 would that also include the frequency and severity of 14 those complications? 15 MR. JONES: Objection. 16 THE DEPONENT: Absolutely. 17 It would include all of the rates and 18 complications -- rates and severity of complications 19 associated with all pelvic floor procedures. 20 BY MR. ROSENBLATT: 21 Q. And what are some of the types of Level 1 22 evidence that you rely on to support your opinions 23 about complication rates, not only just in your 24 practice, but that have been published in medical</p>
Page 115	Page 117
<p>1 BY MR. ROSENBLATT: 2 Q. And where and when do surgeons in their field 3 get this basic understanding of complications 4 associated with pelvic floor surgery? 5 MR. JONES: Objection. 6 THE DEPONENT: The basic complication occurs 7 in medical school and in residency training. 8 BY MR. ROSENBLATT: 9 Q. And then what is the significance, if any, of 10 surgeons in your field keeping up with the medical 11 literature? 12 MR. JONES: Objection. 13 THE DEPONENT: The importance of the surgeons 14 maintaining a contemporary understanding of the medical 15 literature keeps them up-to-date with respect to 16 products that are coming out and techniques that are 17 available for the treatment. 18 BY MR. ROSENBLATT: 19 Q. And would it be fair to say that surgeons in 20 your field do not rely on the instructions for use as 21 the only source of obtaining information about risk? 22 MR. JONES: Objection. 23 THE DEPONENT: I would expect that the 24 surgeons in my field should not rely solely on the</p>	<p>1 literature for the products at issue today? 2 A. The Cochrane database is one. There's an 3 article by Dr. Schrupf, the SGS article. The AUA has 4 a position statement. There is an article -- 5 randomized control trial -- from -- there's -- 6 Q. You say RCTs. What -- what is significant 7 about RCTs or -- strike that. 8 Do you consider RCTs to be Level 1 evidence? 9 MR. JONES: Asked and answered, Paul. 10 THE DEPONENT: Yes. 11 BY MR. ROSENBLATT: 12 Q. And what is the significance about RCTs in 13 your practice? 14 MR. JONES: Objection. 15 THE DEPONENT: They decrease the confounders 16 associated with the study. They decrease bias. They 17 decrease the structure and the methodology -- or they 18 standardize the structure and the methodology, such 19 that the confounders and the conclusions are compelling 20 and reliable. 21 BY MR. ROSENBLATT: 22 Q. And, Doctor, have you reviewed any FDA 23 regulatory guidances that relate to medical device 24 manufacturers --</p>

Joseph M. Carbone, M.D.

Page 118	Page 120
<p>1 MR. JONES: Objection.</p> <p>2 BY MR. ROSENBLATT:</p> <p>3 Q. -- or labeling guidances?</p> <p>4 MR. JONES: Objection.</p> <p>5 BY MR. ROSENBLATT:</p> <p>6 Q. Doctor, when you said -- strike that.</p> <p>7 Doctor, when you said you believed that the</p> <p>8 IFUs should contain risks that are unique to the device</p> <p>9 or specific to the device, what are you relying on for</p> <p>10 that statement?</p> <p>11 MR. JONES: Objection.</p> <p>12 THE DEPONENT: I'm relying on the information</p> <p>13 that I've reviewed regarding the guidelines that are</p> <p>14 set forth with respect to IFUs.</p> <p>15 BY MR. ROSENBLATT:</p> <p>16 Q. And that -- would that be the FDA Blue Book</p> <p>17 of guidance?</p> <p>18 A. I believe it's printed out from the FDA. I</p> <p>19 don't know if it's the Blue Book guidance.</p> <p>20 MR. JONES: Objection. Go ahead and lead</p> <p>21 though.</p> <p>22 BY MR. ROSENBLATT:</p> <p>23 Q. Now, Doctor, I believe you said you had some</p> <p>24 experience teaching prof ed?</p>	<p>1 THE DEPONENT: Yes.</p> <p>2 BY MR. ROSENBLATT:</p> <p>3 Q. And what types of things would you discuss</p> <p>4 with other surgeons in the didactic sessions?</p> <p>5 MR. JONES: Objection.</p> <p>6 THE DEPONENT: We discussed the procedures.</p> <p>7 We discussed the anatomy. We discussed the</p> <p>8 pathophysiology. We discussed complications associated</p> <p>9 with the procedure. We discussed the technique. We</p> <p>10 discussed the literature. And we tried to point out --</p> <p>11 when surgeons came with speculation, we would try to</p> <p>12 provide them with high-level information, or direct</p> <p>13 them to high-level information, that would be</p> <p>14 independent of any Ethicon materials or publications so</p> <p>15 that they can make their own judgment regarding the</p> <p>16 product.</p> <p>17 Q. Why do you rely on high-level medical</p> <p>18 literature?</p> <p>19 A. Well, the high-level medical literature</p> <p>20 provides compelling evidence. It minimizes outliers.</p> <p>21 It collects randomized control trials that minimize</p> <p>22 confounders, and it -- and in the systematic reviews,</p> <p>23 it collects the data from different randomized control</p> <p>24 trials.</p>
Page 119	Page 121
<p>1 A. Yes.</p> <p>2 Q. That would be professional education?</p> <p>3 A. Yes.</p> <p>4 Q. Would you teach surgeons on the instructions</p> <p>5 for use?</p> <p>6 A. Yes.</p> <p>7 Q. And would you walk through the warnings and</p> <p>8 adverse reactions with the surgeons that you were</p> <p>9 teaching?</p> <p>10 A. Yes.</p> <p>11 Q. And did you teach professional education for</p> <p>12 the Prolift?</p> <p>13 A. Yes.</p> <p>14 Q. Did you teach professional education for the</p> <p>15 TVT?</p> <p>16 MR. JONES: Asked and answered, Paul.</p> <p>17 THE DEPONENT: Yes.</p> <p>18 BY MR. ROSENBLATT:</p> <p>19 Q. Did you teach professional education for the</p> <p>20 TVT-O?</p> <p>21 A. Yes.</p> <p>22 Q. And in addition to teaching other surgeons on</p> <p>23 the IFU, would you also go through didactic sessions?</p> <p>24 MR. JONES: Asked and answered.</p>	<p>1 Q. And are your opinions set forth in your</p> <p>2 report about the safety of the design and adequacy of</p> <p>3 the warnings as to Prolift, the TVT, and the TVT-O,</p> <p>4 based on your review of the Level 1 medical literature?</p> <p>5 A. That, and my clinical experience and my</p> <p>6 training.</p> <p>7 Q. Would you also rely on your discussions with</p> <p>8 other surgeons?</p> <p>9 A. Yes.</p> <p>10 MR. JONES: Objection.</p> <p>11 THE DEPONENT: My discussions with other</p> <p>12 surgeons. My interaction with physicians, with</p> <p>13 clinicians. My interactions with my patients.</p> <p>14 BY MR. ROSENBLATT:</p> <p>15 Q. And, Doctor, we looked at Exhibit 5, which is</p> <p>16 a -- it looks like a history of your payments, and I</p> <p>17 believe counsel tallied them up and it came to about</p> <p>18 \$452,000 over a ten-year period. Does that sound</p> <p>19 correct?</p> <p>20 MR. JONES: Object to form.</p> <p>21 THE DEPONENT: Sounds correct.</p> <p>22 BY MR. ROSENBLATT:</p> <p>23 Q. Could you just tell us what type of</p> <p>24 consulting activities you performed for Ethicon between</p>

31 (Pages 118 to 121)

Joseph M. Carbone, M.D.

Page 122	Page 124
<p>1 2003 --</p> <p>2 MR. JONES: Objection. Asked and answered.</p> <p>3 THE DEPONENT: What I did for Ethicon was to</p> <p>4 educate clinicians, and obviously, the sales force,</p> <p>5 with respect to the pathophysiology, with respect to</p> <p>6 the pathologic conditions relating to pelvic floor</p> <p>7 prolapse and relating to stress urinary incontinence,</p> <p>8 and the clinical use of those products for the</p> <p>9 treatment of these conditions.</p> <p>10 Q. Were you proud of the professional education</p> <p>11 work that you did?</p> <p>12 A. I was very proud of the educational work that</p> <p>13 I did.</p> <p>14 Q. Now, if you were spending time teaching other</p> <p>15 surgeons professional education on the Prolift, TVT,</p> <p>16 and TVT-O products, amongst others, would you have to</p> <p>17 forgo the time that you would have spent in your</p> <p>18 clinic?</p> <p>19 MR. JONES: Objection.</p> <p>20 THE DEPONENT: Yes.</p> <p>21 BY MR. ROSENBLATT:</p> <p>22 Q. And would it be fair to say that -- or did it</p> <p>23 provide you any financial -- strike that.</p> <p>24 Did you consider the payments that Ethicon</p>	<p>1 design.</p> <p>2 MR. JONES: Same objection.</p> <p>3 THE DEPONENT: The --</p> <p>4 BY MR. ROSENBLATT:</p> <p>5 Q. I'll strike that.</p> <p>6 Doctor, you're offering opinions about the</p> <p>7 design of Prolift, TVT, and TVT-O. Correct?</p> <p>8 A. Yes.</p> <p>9 Q. And what are your opinions about whether or</p> <p>10 not the designs are safe?</p> <p>11 MR. JONES: Asked and answered, Paul.</p> <p>12 THE DEPONENT: They are safe.</p> <p>13 BY MR. ROSENBLATT:</p> <p>14 Q. And what are you basing that opinion on?</p> <p>15 MR. JONES: Asked and answered.</p> <p>16 THE DEPONENT: I'm basing that opinion on</p> <p>17 medical literature from the Cochrane review comparing</p> <p>18 native tissue repairs to the mesh products. I'm</p> <p>19 referring to the SGS article that, again, compares the</p> <p>20 two. And there are comparable risks with respect to</p> <p>21 dyspareunia pelvic pain.</p> <p>22 BY MR. ROSENBLATT:</p> <p>23 Q. And would it be fair to say you're just</p> <p>24 describing a few studies, but there are a significant</p>
Page 123	Page 125
<p>1 paid to you for your consulting work and teaching other</p> <p>2 surgeons and the sales force, to be fair market value?</p> <p>3 A. It was. In fact, I probably would have made</p> <p>4 more money had I stayed at home.</p> <p>5 Q. So why did you teach professional education</p> <p>6 for Ethicon?</p> <p>7 MR. JONES: Objection.</p> <p>8 THE DEPONENT: Because I enjoyed interacting</p> <p>9 with clinicians. I like interacting with the</p> <p>10 engineers. I like expanding my knowledge base and the</p> <p>11 people I interact with. I'm proud of educating people.</p> <p>12 BY MR. ROSENBLATT:</p> <p>13 Q. And I know you weren't really able to spit</p> <p>14 off the exact pore sizes or the exact weights in</p> <p>15 response to plaintiff's questioning, but would that</p> <p>16 type of information have been contained in the</p> <p>17 professional education materials that you would have</p> <p>18 been teaching at that time?</p> <p>19 MR. JONES: Objection. Form.</p> <p>20 BY MR. ROSENBLATT:</p> <p>21 Q. And when I say "that information," I mean --</p> <p>22 MR. JONES: Same objection.</p> <p>23 BY MR. ROSENBLATT:</p> <p>24 Q. -- product -- information about the product</p>	<p>1 number of other studies?</p> <p>2 MR. JONES: Objection. Leading.</p> <p>3 THE DEPONENT: They're ones I highlight, but</p> <p>4 there are a number of other studies that I reviewed</p> <p>5 that look into that question and collaborate that --</p> <p>6 corroborate those findings.</p> <p>7 BY MR. ROSENBLATT:</p> <p>8 Q. And, Doctor, you told counsel that you</p> <p>9 currently use the TVT Abbrevio and TVT Exact. Is that</p> <p>10 correct?</p> <p>11 A. Yes.</p> <p>12 Q. Are you using the TVT Abbrevio and TVT Exact</p> <p>13 because you have any concerns about the TVT mesh that's</p> <p>14 used in the TVT Retropubic and the TVT-O?</p> <p>15 MR. JONES: Objection. Leading.</p> <p>16 THE DEPONENT: No.</p> <p>17 BY MR. ROSENBLATT:</p> <p>18 Q. Do you have any opinions about whether or not</p> <p>19 the TVT Abbrevio and TVT Exact are safer than the</p> <p>20 TVT Retropubic or TVT-O?</p> <p>21 MR. JONES: Objection. Asked and answered.</p> <p>22 THE DEPONENT: I believe they're equivalent.</p> <p>23 BY MR. ROSENBLATT:</p> <p>24 Q. And, Doctor, are you drawing on your</p>

32 (Pages 122 to 125)

Joseph M. Carbone, M.D.

<p style="text-align: right;">Page 126</p> <p>1 experiences from not only teaching professional</p> <p>2 education and implanting the Prolift, TVT, and TVT-O,</p> <p>3 but also removing some mesh when necessary?</p> <p>4 A. Yes.</p> <p>5 Q. And when you've removed mesh from patients,</p> <p>6 have you ever noticed any type of degradation, particle</p> <p>7 loss, fraying, curling, or roping?</p> <p>8 MR. JONES: Objection. Asked and answered.</p> <p>9 THE DEPONENT: I've never seen any of those.</p> <p>10 BY MR. ROSENBLATT:</p> <p>11 Q. And when you've removed mesh at times, if</p> <p>12 there was mesh in any tissue, did you see good tissue</p> <p>13 integration?</p> <p>14 MR. JONES: Objection.</p> <p>15 THE DEPONENT: Yes.</p> <p>16 MR. JONES: Leading.</p> <p>17 BY MR. ROSENBLATT:</p> <p>18 Q. And counsel asked you a question about does</p> <p>19 Ethicon know more about the design of TVT than you, and</p> <p>20 you responded that, well, you would know more about the</p> <p>21 clinical use. Would you just tell us what you mean by</p> <p>22 drawing on your experiences with the clinical use of</p> <p>23 the design of TVT?</p> <p>24 MR. JONES: Objection.</p>	<p style="text-align: right;">Page 128</p> <p>1 BY MR. ROSENBLATT:</p> <p>2 Q. And when considering the design of a pelvic</p> <p>3 floor mesh as the end user of that design, what</p> <p>4 significance, if any, does the Amid Type 1</p> <p>5 classification have for you regarding the design of the</p> <p>6 mesh?</p> <p>7 A. Well, the Amid Type 1 classification is the</p> <p>8 type of mesh that is most biologically compatible and</p> <p>9 is appropriate for the use, for the treatment of stress</p> <p>10 urinary incontinence and pelvic floor prolapse in</p> <p>11 women.</p> <p>12 Q. Is there any other experience that you have</p> <p>13 with the design of pelvic mesh that we have not</p> <p>14 discussed today?</p> <p>15 MR. JONES: Objection.</p> <p>16 THE DEPONENT: I have spoken with the</p> <p>17 engineers, I have interacted with the surgeons, I have</p> <p>18 taught about the pelvic mesh, and I have learned</p> <p>19 extensively about the pelvic mesh.</p> <p>20 BY MR. ROSENBLATT:</p> <p>21 Q. And someone who has taught not only about the</p> <p>22 design of the mesh, but also the warnings, would you</p> <p>23 consider yourself an expert in the TVT warnings and</p> <p>24 adverse reactions?</p>
<p style="text-align: right;">Page 127</p> <p>1 THE DEPONENT: From an engineering</p> <p>2 standpoint, material science standpoint -- I'm not an</p> <p>3 engineer, but as a surgeon who uses the product, I'm</p> <p>4 aware of how the body reacts to the product, I'm aware</p> <p>5 how the body incorporates the product. I'm aware of</p> <p>6 how the product is safe and effective in the body, and</p> <p>7 in identifying and removing mesh that has eroded, I can</p> <p>8 actually see the incorporation of a tissue in the</p> <p>9 product.</p> <p>10 BY MR. ROSENBLATT:</p> <p>11 Q. Are you drawing on any of your experience</p> <p>12 from using meshes that were not Amid Type 1 meshes?</p> <p>13 A. No.</p> <p>14 MR. JONES: Objection.</p> <p>15 BY MR. ROSENBLATT:</p> <p>16 Q. Are you familiar with complications that are</p> <p>17 associated with meshes that are not Amid Type 1 meshes?</p> <p>18 A. Yes.</p> <p>19 Q. And how do the complications with those</p> <p>20 meshes that are not Amid Type 1 compare to meshes like</p> <p>21 TVT and Prolift that are Amid Type 1?</p> <p>22 MR. JONES: Objection. Leading.</p> <p>23 THE DEPONENT: The complications are much</p> <p>24 higher in non-Amid Type 1 meshes.</p>	<p style="text-align: right;">Page 129</p> <p>1 A. Yes. He had asked that.</p> <p>2 Q. And would the same be true --</p> <p>3 MR. JONES: Good point.</p> <p>4 BY MR. ROSENBLATT:</p> <p>5 Q. -- for Prolift?</p> <p>6 MR. JONES: Objection. Asked and answered</p> <p>7 again.</p> <p>8 THE DEPONENT: Yes.</p> <p>9 BY MR. ROSENBLATT:</p> <p>10 Q. Counsel also asked you questions about</p> <p>11 whether or not you analyzed Ethicon internal complaints</p> <p>12 about the various complications. And my question to</p> <p>13 you is: Have you analyzed the Level 1 evidence that's</p> <p>14 been published in the peer reviewed literature for</p> <p>15 complications associated with Prolift, TVT, and TVT-O?</p> <p>16 MR. JONES: Same Objection.</p> <p>17 THE DEPONENT: Yes.</p> <p>18 BY MR. ROSENBLATT:</p> <p>19 Q. And are the complications that are reported</p> <p>20 in the medical literature for the most part consistent</p> <p>21 with your clinical experience?</p> <p>22 A. Yes.</p> <p>23 Q. Now, there were several agreements that we</p> <p>24 looked at. I want to show you Exhibit 9.</p>

33 (Pages 126 to 129)

Joseph M. Carbone, M.D.

Page 130	Page 132
<p>1 Counsel had you read Section 9-B, but just a</p> <p>2 portion of it. What is the first sentence that counsel</p> <p>3 did not read?</p> <p>4 A. "For consulting activities for EG, cadaveric</p> <p>5 labs, telesurgery, and proctorship, et cetera,</p> <p>6 compensation will be determined based on the extent of</p> <p>7 travel required and the amount of time preceptor is</p> <p>8 required to be away from the office."</p> <p>9 Q. Now, would it be fair to say that if you were</p> <p>10 teaching other surgeons, that you weren't always able</p> <p>11 to do that in your own office?</p> <p>12 MR. JONES: Objection. Leading.</p> <p>13 THE DEPONENT: Yes.</p> <p>14 BY MR. ROSENBLATT:</p> <p>15 Q. And would you expect to be compensated for</p> <p>16 your time out of the office if you're training another</p> <p>17 surgeon?</p> <p>18 MR. JONES: Objection. Asked and answered.</p> <p>19 THE DEPONENT: Yes.</p> <p>20 BY MR. ROSENBLATT:</p> <p>21 Q. Counsel also mentioned something about you</p> <p>22 weren't allowed to discuss anything unless it was</p> <p>23 approved by Ethicon. Was there anything, while you</p> <p>24 were teaching professional education, that you felt you</p>	<p>1 BY MR. ROSENBLATT:</p> <p>2 Q. And when you were at this AUA meeting in 2004</p> <p>3 at the booth, was that an opportunity for you to</p> <p>4 interact with other surgeons?</p> <p>5 MR. JONES: Objection. Leading.</p> <p>6 THE DEPONENT: Absolutely.</p> <p>7 MR. JONES: Just let me get my objection in,</p> <p>8 sorry, so I don't talk over you.</p> <p>9 That was a leading objection.</p> <p>10 MR. ROSENBLATT: That's all I have for right</p> <p>11 now.</p> <p>12 MR. JONES: Are you ready, Doctor? I promise</p> <p>13 this is it, unless he's got more questions, then it may</p> <p>14 not be it. Okay?</p> <p>15 THE DEPONENT: Make them good, and I won't.</p> <p>16 MR. JONES: I'm going to try, Paul.</p> <p>17</p> <p>18 FURTHER EXAMINATION</p> <p>19 BY MR. JONES:</p> <p>20 Q. All right. You've mentioned with Ethicon's</p> <p>21 attorney that your success rates were actually higher</p> <p>22 than what was reported in the literature. Correct?</p> <p>23 MR. ROSENBLATT: Object to form. I think</p> <p>24 that misstates his testimony.</p>
Page 131	Page 133
<p>1 wanted to express to surgeons but you felt that Ethicon</p> <p>2 did not let you tell them?</p> <p>3 MR. JONES: Objection. Leading. Go on.</p> <p>4 THE DEPONENT: I wanted to make some jokes in</p> <p>5 my presentations, but regarding the clinical</p> <p>6 information that I was presenting, no.</p> <p>7 BY MR. ROSENBLATT:</p> <p>8 Q. Exhibit 15, counsel pointed out a statement</p> <p>9 from Mr. Steele. "Thank you for thinking of us and</p> <p>10 being a such a good partner and customer."</p> <p>11 What did he say right before that?</p> <p>12 A. "Your dedication to your professor" --</p> <p>13 "profession and as an educator are to be admired."</p> <p>14 Q. Now, do you think this e-mail suggests any</p> <p>15 impropriety about you --</p> <p>16 MR. JONES: Objection.</p> <p>17 BY MR. ROSENBLATT:</p> <p>18 Q. -- being bought and paid for by Ethicon?</p> <p>19 MR. JONES: Objection. Leading.</p> <p>20 THE DEPONENT: No.</p> <p>21 BY MR. ROSENBLATT:</p> <p>22 Q. Did you ever feel that way?</p> <p>23 A. No.</p> <p>24 MR. JONES: Same objection.</p>	<p>1 BY MR. JONES:</p> <p>2 Q. What was your testimony? Tell me.</p> <p>3 A. Complication rate's below it.</p> <p>4 Q. Your complication rate with Ethicon mesh</p> <p>5 products is lower than what's reported in the</p> <p>6 literature, as you represented that to Ethicon's</p> <p>7 attorney just now. Correct?</p> <p>8 A. A little bit lower, yes.</p> <p>9 Q. So it's fair to say then, your complication</p> <p>10 rate compared to the complication rate reported in the</p> <p>11 literature, you're an outlier?</p> <p>12 A. I don't know if it's statistically</p> <p>13 significantly lower.</p> <p>14 Q. Are you an outlier when it comes to</p> <p>15 complication rate?</p> <p>16 MR. ROSENBLATT: Object to form.</p> <p>17 THE DEPONENT: I don't think so.</p> <p>18 BY MR. JONES:</p> <p>19 Q. You don't consider yourself an outlier at all</p> <p>20 when it comes to Ethicon mesh complication rates?</p> <p>21 A. I'd have to do the statistical analysis.</p> <p>22 Q. And you haven't done that?</p> <p>23 A. I have not done that.</p> <p>24 Q. Okay. Today you met with Mr. Rosenblatt.</p>

34 (Pages 130 to 133)

Joseph M. Carbone, M.D.

Page 134	Page 136
<p>1 Correct?</p> <p>2 A. Yes.</p> <p>3 Q. And did you talk about, at all, those binders</p> <p>4 of documents?</p> <p>5 A. Those binders of documents?</p> <p>6 Q. Uh-huh.</p> <p>7 A. No.</p> <p>8 Q. Talk about it with him last night?</p> <p>9 A. No.</p> <p>10 Q. Are you sure?</p> <p>11 A. The binders?</p> <p>12 Q. Those documents sitting over there.</p> <p>13 A. The documents?</p> <p>14 Q. At all.</p> <p>15 A. I don't recall specifically.</p> <p>16 Q. Don't recall one way or the other.</p> <p>17 A. No.</p> <p>18 MR. ROSENBLATT: Nate, I'll represent to you,</p> <p>19 these boxes have been sitting there. We did not --</p> <p>20 MR. JONES: Yeah. I remember Mr. Moriarty</p> <p>21 said we were all desperate if we looked at them</p> <p>22 yesterday.</p> <p>23 BY MR. JONES:</p> <p>24 Q. Now, yesterday you said you reviewed ten to</p>	<p>1 BY MR. JONES:</p> <p>2 Q. You get what I'm getting at, Doctor, don't</p> <p>3 you?</p> <p>4 A. I really don't.</p> <p>5 Q. You don't?</p> <p>6 A. No.</p> <p>7 Q. Okay. You have referenced binders of</p> <p>8 documents tonight. Correct?</p> <p>9 A. Yes.</p> <p>10 Q. Are you prepared to answer questions about</p> <p>11 all of the materials in those binders tonight?</p> <p>12 A. Am I prepared? If you want to go through</p> <p>13 them all, I'll answer the questions with you.</p> <p>14 Q. Okay. So when it comes time for trial,</p> <p>15 you're going to be able to answer questions about every</p> <p>16 single material that's in those binders. Correct?</p> <p>17 MR. ROSENBLATT: Object to form.</p> <p>18 THE DEPONENT: If you hand them to me, I'll</p> <p>19 be able to discuss them.</p> <p>20 BY MR. JONES:</p> <p>21 Q. So at trial, if I go through those binders</p> <p>22 and I pull out -- some materials out of those binders,</p> <p>23 you're going to answer questions about them when you're</p> <p>24 on the witness stand at trial. Correct? Fair. Right?</p>
Page 135	Page 137
<p>1 fifteen internal corporate Ethicon documents. You told</p> <p>2 me that. Correct?</p> <p>3 A. Correct.</p> <p>4 Q. All right. Today, after meeting with</p> <p>5 Mr. Rosenblatt, it's your testimony that you're going</p> <p>6 to be prepared to answer questions about every single</p> <p>7 document that's in those binders over there. Correct?</p> <p>8 MR. ROSENBLATT: Object to form. Misstates</p> <p>9 his testimony.</p> <p>10 BY MR. JONES:</p> <p>11 Q. Are you prepared to answer questions about</p> <p>12 every single document that's in those binders over</p> <p>13 there?</p> <p>14 A. No.</p> <p>15 Q. No, you're not?</p> <p>16 A. Not on every detail of every document in</p> <p>17 those binders at this -- you know, at a moment's</p> <p>18 notice.</p> <p>19 Q. Okay. That's fair. That's fair.</p> <p>20 So you're not prepared to answer questions</p> <p>21 about every single document in these binders. Correct?</p> <p>22 MR. ROSENBLATT: Object to form about answer</p> <p>23 questions.</p> <p>24 MR. JONES: Thanks.</p>	<p>1 A. They're on my reliance list.</p> <p>2 Q. Let's look at your reliance list.</p> <p>3 Turn to -- well, I'll turn to it for you.</p> <p>4 Other than medical literature, are the</p> <p>5 materials listed in your reliance list all of the</p> <p>6 internal documents that you're relying on in this</p> <p>7 litigation for your opinions, yes or no?</p> <p>8 A. I'm sorry?</p> <p>9 Q. Other than medical literature and your</p> <p>10 clinical expertise and experience, are the internal</p> <p>11 Ethicon documents listed -- that you've listed on your</p> <p>12 reliance list all of the internal Ethicon documents</p> <p>13 that you're relying on for your opinions in this case?</p> <p>14 A. I've reviewed a significant number of Ethicon</p> <p>15 documents, so it extends beyond these.</p> <p>16 Q. Okay. So yesterday you did tell us you</p> <p>17 reviewed 15 to 20 internal Ethicon documents. Correct?</p> <p>18 A. Yes.</p> <p>19 Q. Okay. Today you met with Mr. Rosenblatt for</p> <p>20 a couple hours. Correct?</p> <p>21 A. Yes.</p> <p>22 Q. And now it's -- you're changing your</p> <p>23 testimony. Correct?</p> <p>24 A. No.</p>

35 (Pages 134 to 137)

Joseph M. Carbone, M.D.

<p style="text-align: right;">Page 138</p> <p>1 MR. ROSENBLATT: Nate, Nate --</p> <p>2 MR. JONES: Stop, Paul. No more speaking</p> <p>3 objections, Paul.</p> <p>4 MR. ROSENBLATT: There's a difference between</p> <p>5 relying and reviewing.</p> <p>6 MR. JONES: Oh, there is? Thanks for that</p> <p>7 speaking objection, Paul.</p> <p>8 BY MR. JONES:</p> <p>9 Q. Are you changing your testimony at all today</p> <p>10 related to what internal Ethicon documents you're</p> <p>11 relying on to support your opinions in this litigation?</p> <p>12 A. No.</p> <p>13 Q. Okay. You're not changing your testimony at</p> <p>14 all from last night?</p> <p>15 A. Not that I'm -- no.</p> <p>16 Q. Okay. Do you know when the ICD-9 code was</p> <p>17 initiated?</p> <p>18 A. When the ICD-9 code was initiated?</p> <p>19 Q. Yes. That's the question.</p> <p>20 A. Before I started my -- before I started</p> <p>21 practicing medicine.</p> <p>22 Q. Okay. When was the -- and has it always been</p> <p>23 the same, covered the same complications?</p> <p>24 A. No. The ICD-9 codes get modified from time</p>	<p style="text-align: right;">Page 140</p> <p>1 BY MR. JONES:</p> <p>2 Q. Abbott, are you familiar with that article?</p> <p>3 A. I've probably reviewed it.</p> <p>4 Q. You've probably reviewed it. So if I asked</p> <p>5 you about the Abbott article at trial, you'll be ready</p> <p>6 to talk about it. Correct?</p> <p>7 MR. ROSENBLATT: Now he is.</p> <p>8 THE DEPONENT: Yeah.</p> <p>9 BY MR. JONES:</p> <p>10 Q. Okay. What about Elliott, the Elliott</p> <p>11 article, are you familiar with that one?</p> <p>12 A. I've probably reviewed it.</p> <p>13 Q. You've probably reviewed it, so you'll be</p> <p>14 ready to talk about it?</p> <p>15 A. Yeah.</p> <p>16 Q. Perfect. And are you aware of what the</p> <p>17 conclusions are in those two articles?</p> <p>18 A. Not at this time. Not off the top of my</p> <p>19 head.</p> <p>20 Q. Okay. But you're familiar with the</p> <p>21 phenomenon reported in the medical literature of</p> <p>22 physicians not knowing their success rates when it</p> <p>23 comes to transvaginal mesh?</p> <p>24 MR. ROSENBLATT: Object to form.</p>
<p style="text-align: right;">Page 139</p> <p>1 to time.</p> <p>2 Q. So over time to time, the ICD-9 codes get</p> <p>3 modified. Correct?</p> <p>4 A. Yes.</p> <p>5 Q. When did the IC -- ICD-10 code come about?</p> <p>6 A. Last year -- well, no. Wait. When was it</p> <p>7 incorporated into the United States? Last year.</p> <p>8 Q. Okay. Are you familiar with medical</p> <p>9 literature that concludes physicians often exaggerate</p> <p>10 their success rates?</p> <p>11 A. I'm sorry?</p> <p>12 Q. Are you familiar with any medical literature</p> <p>13 that concludes physicians often exaggerate their</p> <p>14 success rates related to transvaginal mesh procedures?</p> <p>15 MR. ROSENBLATT: Object to form.</p> <p>16 THE DEPONENT: I've probably reviewed some.</p> <p>17 BY MR. JONES:</p> <p>18 Q. You probably have reviewed those articles?</p> <p>19 A. I probably looked at them.</p> <p>20 Q. If I asked you about those articles at trial,</p> <p>21 you've probably reviewed them. Correct?</p> <p>22 MR. ROSENBLATT: Why don't you let him know</p> <p>23 which article you're talking about?</p> <p>24</p>	<p style="text-align: right;">Page 141</p> <p>1 THE DEPONENT: I am familiar with what?</p> <p>2 BY MR. JONES:</p> <p>3 Q. Medical literature that concludes physicians,</p> <p>4 like yourself, aren't familiar, don't know the success</p> <p>5 rates with their patients when they use transvaginal</p> <p>6 mesh.</p> <p>7 A. I probably reviewed it.</p> <p>8 Q. Okay. And why is it that physicians don't</p> <p>9 know their success rates when it comes to their use of</p> <p>10 transvaginal mesh?</p> <p>11 MR. ROSENBLATT: Object to form. Lack of</p> <p>12 foundation.</p> <p>13 THE DEPONENT: I don't know.</p> <p>14 BY MR. JONES:</p> <p>15 Q. You don't know. Could it be because they</p> <p>16 don't track their patients?</p> <p>17 A. I mean, you can speculate that.</p> <p>18 Q. You can speculate, but you don't know, as you</p> <p>19 sit here today?</p> <p>20 A. No.</p> <p>21 Q. Okay. Are you aware that the professional</p> <p>22 education department at Ethicon is within the marketing</p> <p>23 division?</p> <p>24 A. No.</p>

36 (Pages 138 to 141)

Joseph M. Carbone, M.D.

Page 142	Page 144
<p>1 MR. ROSENBLATT: And, Nate, I'm showing</p> <p>2 you've got time, but if you've got a couple more</p> <p>3 questions, you can --</p> <p>4 MR. JONES: Paul, there is no way you're</p> <p>5 going to limit me on time per the two hours at all.</p> <p>6 How are you supposed to know -- I had no idea how much</p> <p>7 time you were going to spend on direct, so how are you</p> <p>8 going to arbitrarily limit my time on something that</p> <p>9 I'm completely dependent on you?</p> <p>10 You're the one that decided to do a direct</p> <p>11 where you ask questions, "What are your opinions, is it</p> <p>12 safe or not?"</p> <p>13 You did an extremely broad direct.</p> <p>14 MR. ROSENBLATT: Look, you had his expert</p> <p>15 report, and I took a deposition on Monday, and the</p> <p>16 attorneys for plaintiffs did that to me, too. So this</p> <p>17 is not something --</p> <p>18 MR. JONES: Well, I'm not that attorney. I'm</p> <p>19 not that attorney, Paul.</p> <p>20 MR. ROSENBLATT: Well, you keep saying,</p> <p>21 "Well, William did something." I wasn't the attorney</p> <p>22 there. I'm just telling you how things have been in my</p> <p>23 experience.</p> <p>24 MR. JONES: But William -- you work with</p>	<p>1 made -- you referenced that sometimes they made you</p> <p>2 take out jokes.</p> <p>3 A. Humor.</p> <p>4 Q. Humor. So if we went back and we looked at</p> <p>5 some of the materials you presented at the Gynecare</p> <p>6 sales school, is it fair that Ethicon approved those</p> <p>7 materials for you to use?</p> <p>8 A. Yes.</p> <p>9 Q. Okay. And can you remember anytime where</p> <p>10 Ethicon told -- erased or eliminated certain humor from</p> <p>11 your presentations?</p> <p>12 A. No.</p> <p>13 Q. Is native tissue repair the gold standard for</p> <p>14 pelvic organ prolapse today?</p> <p>15 MR. ROSENBLATT: Object to form. Outside the</p> <p>16 scope. I will give you another minute.</p> <p>17 MR. JONES: No. It's not outside the scope</p> <p>18 at all.</p> <p>19 MR. ROSENBLATT: Yeah.</p> <p>20 MR. JONES: We'll go back over the record.</p> <p>21 MR. ROSENBLATT: You've got a minute, but...</p> <p>22 THE DEPONENT: The gold standard is a --</p> <p>23 MR. JONES: This isn't counting against my</p> <p>24 time either.</p>
Page 143	Page 145
<p>1 William, Paul. Come on.</p> <p>2 MR. ROSENBLATT: I don't go into his office</p> <p>3 and say --</p> <p>4 MR. JONES: I'm going to keep going. Hey,</p> <p>5 I'm going to keep going. I will do my best to hurry</p> <p>6 up. Okay?</p> <p>7 MR. ROSENBLATT: I will give you a few more</p> <p>8 minutes.</p> <p>9 MR. JONES: You did an extremely broad</p> <p>10 direct, and I'm going to follow up on every issue you</p> <p>11 asked in direct. And if you cut me off -- if you cut</p> <p>12 me off, you've got to cut me off.</p> <p>13 MR. ROSENBLATT: You're wasting your time.</p> <p>14 MR. JONES: Thanks.</p> <p>15 BY MR. JONES:</p> <p>16 Q. Professional education, you talked about that</p> <p>17 with Paul. Right? Yes or no.</p> <p>18 A. Professional education.</p> <p>19 Q. Yeah, you did.</p> <p>20 Now, and every single professional education</p> <p>21 event you did, Ethicon had to approve the materials you</p> <p>22 used. Correct?</p> <p>23 A. Yes.</p> <p>24 Q. Okay. And so the materials -- and you</p>	<p>1 THE DEPONENT: Okay.</p> <p>2 MR. JONES: Just sit there and think about</p> <p>3 it.</p> <p>4 THE DEPONENT: The native tissue repair is</p> <p>5 the most common at this point.</p> <p>6 BY MR. JONES:</p> <p>7 Q. Okay. And the \$450,000 that Ethicon paid you</p> <p>8 as a consultant, that includes payments for marketing</p> <p>9 events. Correct?</p> <p>10 A. I believe so.</p> <p>11 Q. And the \$450,000 that Ethicon paid you to be</p> <p>12 a consultant for them, that was a financial benefit to</p> <p>13 you. Correct?</p> <p>14 A. Maybe not.</p> <p>15 MR. ROSENBLATT: Object to form.</p> <p>16 BY MR. JONES:</p> <p>17 Q. Maybe not.</p> <p>18 Is \$450,000 a lot of money?</p> <p>19 MR. ROSENBLATT: Object to form.</p> <p>20 THE DEPONENT: I probably could have made</p> <p>21 more money if I stayed home.</p> <p>22 BY MR. JONES:</p> <p>23 Q. Was the Napa Valley trip included in that</p> <p>24 \$450,000, yes or no?</p>

37 (Pages 142 to 145)

Joseph M. Carbone, M.D.

Page 146	Page 148
<p>1 MR. ROSENBLATT: Object to form.</p> <p>2 THE DEPONENT: Travel to the Napa Valley was</p> <p>3 included.</p> <p>4 MR. ROSENBLATT: Nate, one more question.</p> <p>5 BY MR. JONES:</p> <p>6 Q. Are dinner events included --</p> <p>7 This is my last question.</p> <p>8 Are dinner events --</p> <p>9 MR. ROSENBLATT: Make it good.</p> <p>10 MR. JONES: Okay. Then I'm going to think</p> <p>11 about it then. If you really cut me off after this</p> <p>12 question --</p> <p>13 MR. ROSENBLATT: I am, yeah.</p> <p>14 MR. JONES: You really are, Paul? I think</p> <p>15 that's extremely unfair, based on your direct. I get</p> <p>16 your position, but I'm just telling you what my</p> <p>17 position is. I think it's extremely unfair.</p> <p>18 MR. ROSENBLATT: Two more questions. Come</p> <p>19 on. Let's go.</p> <p>20 BY MR. JONES:</p> <p>21 Q. Doctor, before you used TVT Secure, did you</p> <p>22 do a review of the literature on TVT Secure?</p> <p>23 MR. ROSENBLATT: Object to form. Outside the</p> <p>24 scope.</p>	<p>1 the other?</p> <p>2 MR. ROSENBLATT: Okay. We're good. We're</p> <p>3 good. We're shutting down.</p> <p>4 MR. FAES: Hold on, Paul, but I've got a few</p> <p>5 questions myself.</p> <p>6 MR. ROSENBLATT: No. We're not doing the</p> <p>7 two-person thing. We're going to move on to case</p> <p>8 specific.</p> <p>9 MR. JONES: He's got Prolift.</p> <p>10 MR. FAES: He's offered new opinions. I</p> <p>11 don't need a whole lot of time. I guarantee it will be</p> <p>12 under ten minutes. It will probably closer to five.</p> <p>13 MR. ROSENBLATT: All right.</p> <p>14 MR. FAES: But you've gone on the record --</p> <p>15 MR. ROSENBLATT: Go ahead, Andy. I'm not</p> <p>16 fussing. Let's go.</p> <p>17</p> <p>18 EXAMINATION</p> <p>19 BY MR. FAES:</p> <p>20 Q. Doctor -- do you need a quick break, Doctor?</p> <p>21 Are you okay?</p> <p>22 A. Go ahead.</p> <p>23 Q. I guarantee I won't be more than ten minutes.</p> <p>24 Okay?</p>
Page 147	Page 149
<p>1 MR. JONES: Was it? You asked him, Paul, in</p> <p>2 your direct whether doctors are responsible for keeping</p> <p>3 up with the medical literature on products they used.</p> <p>4 I'm asking him if he does it.</p> <p>5 BY MR. JONES:</p> <p>6 Q. Before you used the TVT Secure, did you do a</p> <p>7 literature review on TVT Secure?</p> <p>8 A. I reviewed the IFU.</p> <p>9 Q. Motion to strike. That was not the question,</p> <p>10 Doctor.</p> <p>11 Before you used TVT Secure, did you do a</p> <p>12 literature review on TVT Secure, yes or no?</p> <p>13 A. I reviewed the IFU, which is a no to your</p> <p>14 answer.</p> <p>15 MR. ROSENBLATT: All right. That's it.</p> <p>16 MR. JONES: That was one question, Paul.</p> <p>17 I've got one more.</p> <p>18 BY MR. JONES:</p> <p>19 Q. Are doctors taught in medical school the pore</p> <p>20 size, weight, or properties of Ethicon mesh?</p> <p>21 A. Currently?</p> <p>22 Q. Yeah.</p> <p>23 A. Probably.</p> <p>24 Q. Probably. Do you know for sure one way or</p>	<p>1 Doctor, is it your opinion that professional</p> <p>2 education or literature review can be a substitute for</p> <p>3 the IFU in providing information about risks and</p> <p>4 complications to physicians?</p> <p>5 A. You know what? I'm going to ask you to</p> <p>6 repeat your question.</p> <p>7 MR. FAES: Could I have the court reporter</p> <p>8 read back the question, please?</p> <p>9 You know what? I can do it, if it's easier.</p> <p>10 BY MR. FAES:</p> <p>11 Q. Doctor, is it your opinion that professional</p> <p>12 education or literature review can be a substitute for</p> <p>13 the IFU in providing information about risks and</p> <p>14 complications to physicians?</p> <p>15 A. Yes.</p> <p>16 Q. Do you know if, under the federal rules of</p> <p>17 regulatory guidance, if Ethicon is allowed to provide</p> <p>18 information in a source other than the IFU as a</p> <p>19 substitute if that information is required to be in the</p> <p>20 IFU?</p> <p>21 MR. ROSENBLATT: Object to form.</p> <p>22 THE DEPONENT: Required to be in the IFU? I</p> <p>23 don't understand that question.</p> <p>24 MR. FAES: All right. I'll ask it again.</p>

38 (Pages 146 to 149)

Joseph M. Carbone, M.D.

Page 150	Page 152
<p>1 BY MR. FAES:</p> <p>2 Q. Do you know if, under the federal rules of</p> <p>3 regulatory guidance --</p> <p>4 A. Okay.</p> <p>5 Q. -- if Ethicon is required to provide risk</p> <p>6 information -- strike that.</p> <p>7 Do you know if, under the federal rule of</p> <p>8 regulatory guidance, if Ethicon was allowed to provide</p> <p>9 information in a source other than the IFU, such as</p> <p>10 professional education or a review of the literature,</p> <p>11 if that -- as a substitute, if that information was</p> <p>12 required to be in the IFU under the rule of regulatory</p> <p>13 guidance?</p> <p>14 MR. ROSENBLATT: Objection to form.</p> <p>15 THE DEPONENT: If it's supposed to be in the</p> <p>16 IFU, it's supposed to be in the IFU.</p> <p>17 BY MR. FAES:</p> <p>18 Q. Right.</p> <p>19 A. I don't think you can substitute --</p> <p>20 Q. You would agree -- let me see if I can</p> <p>21 simplify it.</p> <p>22 If the rules require it -- if the federal</p> <p>23 rules or regulations require it to be in the IFU, then</p> <p>24 you agree that Ethicon can't rely on professional</p>	<p>1 THE DEPONENT: What kind of certain type of</p> <p>2 information are you talking about?</p> <p>3 See, you said --</p> <p>4 BY MR. FAES:</p> <p>5 Q. The information that if they're -- if the FDA</p> <p>6 determines they're required to put it in the IFU.</p> <p>7 MR. ROSENBLATT: Object to form.</p> <p>8 BY MR. FAES:</p> <p>9 Q. If they're required to put it in the IFU</p> <p>10 under the rules or guidance.</p> <p>11 MR. ROSENBLATT: Object to the representation</p> <p>12 that guidance requires.</p> <p>13 THE DEPONENT: Yeah. I mean, it's guidance.</p> <p>14 I mean, it's guidance. I mean, if you were saying to</p> <p>15 me -- I mean, it's hypothetical. If you were saying</p> <p>16 they were required to put it into the IFU, then they</p> <p>17 were required to put it in the IFU.</p> <p>18 BY MR. FAES:</p> <p>19 Q. Right.</p> <p>20 A. Yes. Then -- yes.</p> <p>21 Q. Says they have to put it into the IFU?</p> <p>22 A. No, not have to. Required to.</p> <p>23 Q. So if the guidance says they're required to</p> <p>24 put it in the IFU, then Ethicon can't rely on</p>
Page 151	Page 153
<p>1 education or some other source. Correct?</p> <p>2 MR. ROSENBLATT: Object to form.</p> <p>3 THE DEPONENT: For the -- for the</p> <p>4 complications specific to the product to the Prolift,</p> <p>5 but not for complications not specific to the product.</p> <p>6 So your question is very board.</p> <p>7 Yes, in fact, reasonable pelvic floor</p> <p>8 surgeons should not rely solely on the IFU, but the IFU</p> <p>9 has to have the complications specifically associated</p> <p>10 with the product.</p> <p>11 BY MR. FAES:</p> <p>12 Q. That's not my question.</p> <p>13 A. But I don't understand your question.</p> <p>14 Q. My question is: If under the federal rules</p> <p>15 or regulatory guidance that Ethicon is required to</p> <p>16 provide certain type of risk information in the IFU --</p> <p>17 A. Specific to?</p> <p>18 Q. The Prolift.</p> <p>19 A. The Prolift.</p> <p>20 Q. -- can they rely on the fact that that</p> <p>21 information is in another source, such as professional</p> <p>22 education or the literature and then not put that in</p> <p>23 the IFU?</p> <p>24 MR. ROSENBLATT: Object to form. Vague.</p>	<p>1 professional education or literature as a substitute?</p> <p>2 MR. ROSENBLATT: Object to form.</p> <p>3 THE DEPONENT: That's not -- if they were</p> <p>4 required to put it in IFU, then they're required to put</p> <p>5 it in the IFU.</p> <p>6 MR. FAES: Okay. Fair enough.</p> <p>7 BY MR. FAES:</p> <p>8 Q. You've talked about your systematic review of</p> <p>9 your charts and that you came up with complication</p> <p>10 rates for -- your personal complication rates for your</p> <p>11 products. Is that correct?</p> <p>12 A. I looked at a number of different ICD-9 codes</p> <p>13 and ICD-10 codes. Some of the ICD-9 codes don't go as</p> <p>14 far back as when I started. It's true.</p> <p>15 I mean, I looked at like a survey of a couple</p> <p>16 of years back and extrapolated based on the number of</p> <p>17 procedures that I've done. You're absolutely right, I</p> <p>18 didn't do a systematic review.</p> <p>19 I mean, a systematic review rises -- I mean,</p> <p>20 you know, I didn't do a systematic review, no. I don't</p> <p>21 believe I said I did a systematic review.</p> <p>22 Q. Fair enough.</p> <p>23 Did you do this review for both the TVT</p> <p>24 family of products and the Prolift?</p>

39 (Pages 150 to 153)

Joseph M. Carbone, M.D.

Page 154	Page 156
<p>1 A. I did the review based on the ICD-9 code for</p> <p>2 mesh exposure.</p> <p>3 Q. So is the answer no, you didn't do it</p> <p>4 specifically to the TVT family of products. Is that</p> <p>5 correct?</p> <p>6 MR. ROSENBLATT: Object to form. Misstates</p> <p>7 his testimony.</p> <p>8 THE DEPONENT: I'm sorry. What was the</p> <p>9 question?</p> <p>10 MR. FAES: I'll withdraw that question and</p> <p>11 ask another one.</p> <p>12 BY MR. FAES:</p> <p>13 Q. You said earlier, when Mr. Rosenblatt was</p> <p>14 questioning you, that you believe your patient</p> <p>15 follow-up is pretty high?</p> <p>16 A. I believe so.</p> <p>17 Q. Is that an opinion you intend to offer at</p> <p>18 trial?</p> <p>19 A. That I believe it's pretty high?</p> <p>20 Q. Yes.</p> <p>21 A. Yeah. I believe it's pretty high.</p> <p>22 Q. You believe you can state that to a</p> <p>23 reasonable degree of medical certainty, that your</p> <p>24 follow-up rate is pretty high?</p>	<p>1 Doctor, there's no question pending.</p> <p>2 Doctor, is mesh roping or curling a unique</p> <p>3 risk to the Prolift?</p> <p>4 MR. ROSENBLATT: Object to form.</p> <p>5 THE DEPONENT: When -- you know, when used</p> <p>6 properly -- I mean, again, you know. Again, when used</p> <p>7 properly, it's not a risk to the Prolift.</p> <p>8 BY MR. FAES:</p> <p>9 Q. So is it your opinion that the only way that</p> <p>10 the mesh arms of the Prolift can become roped or curled</p> <p>11 when they're passed with the cannula is if it's done</p> <p>12 incorrectly?</p> <p>13 A. When the cannula is removed, the mesh lies</p> <p>14 flat.</p> <p>15 Q. That was not my question. My question was:</p> <p>16 Do you believe that the only way that the mesh arms can</p> <p>17 become roped or curled when they're passed with the</p> <p>18 cannula is if the physician does it incorrectly?</p> <p>19 A. I don't believe the mesh arms become roped or</p> <p>20 curled.</p> <p>21 Q. You've never seen documents --</p> <p>22 A. I've never --</p> <p>23 Q. -- or any opinions from Ethicon medical</p> <p>24 directors that state that the mesh in the Prolift arms</p>
Page 155	Page 157
<p>1 A. You know, greater than 50 percent follow-up</p> <p>2 with me.</p> <p>3 Q. My question was: Do you believe you can</p> <p>4 state to a reasonable degree of medical certainty that</p> <p>5 your patient follow-up is pretty high?</p> <p>6 A. I believe I can.</p> <p>7 Q. So what is your patient follow-up rate, and</p> <p>8 how did you determine that?</p> <p>9 A. I think it's greater than half, and I</p> <p>10 determined it based on --</p> <p>11 Q. Can you be any more specific than greater</p> <p>12 than half? Do you have a percentage?</p> <p>13 A. No, I don't.</p> <p>14 Q. Do you know what follow-up rates are for</p> <p>15 physicians in your area?</p> <p>16 A. For physicians in my area, no.</p> <p>17 Q. Do you know what average follow-up rates are</p> <p>18 for physicians -- general physicians around the rest of</p> <p>19 the country?</p> <p>20 Strike that. Do you know what --</p> <p>21 A. I know there's a study --</p> <p>22 Q. Actually, I struck that.</p> <p>23 A. -- a randomized controlled study --</p> <p>24 Q. You don't need to answer that.</p>	<p>1 can become deformed or curled or roped?</p> <p>2 A. Nothing that, you know, has the scientific</p> <p>3 rigor. I mean, you know, everybody can have their</p> <p>4 opinion. I'm sorry, everybody can speculate.</p> <p>5 Q. So is the answer to my question, yes, you</p> <p>6 don't know what Ethicon scientists and engineers</p> <p>7 thought about whether or not the Prolift mesh arms</p> <p>8 could become roped or curled or deformed when passed</p> <p>9 with the cannula?</p> <p>10 A. I don't know what they thought, what their</p> <p>11 speculation was.</p> <p>12 Q. Are you aware that Dr. Amid doesn't think his</p> <p>13 standard applies to the type of mesh that's used in the</p> <p>14 TVT or the Prolift?</p> <p>15 MR. ROSENBLATT: Objection. Lack of</p> <p>16 foundation.</p> <p>17 THE DEPONENT: I'm not aware of that.</p> <p>18 MR. FAES: The only other thing I have is, I</p> <p>19 am going to go ahead and mark these binders in your</p> <p>20 boxes as an exhibit.</p> <p>21 What exhibit number are we on?</p> <p>22 THE COURT REPORTER: I think the next one is</p> <p>23 going to be 18.</p> <p>24 MR. FAES: So all the materials over there</p>

40 (Pages 154 to 157)

Joseph M. Carbone, M.D.


<p style="text-align: center;">Page 158</p> <p>1 will be marked as Exhibit 18, and we'll send those off</p> <p>2 with the court reporter to be scanned. And that's all</p> <p>3 the questions I have.</p> <p>4 Thank you, Dr. Carbone.</p> <p>5 (Three banker boxes of exhibit notebooks were</p> <p>6 marked collective for identification as Carbone</p> <p>7 Deposition Exhibits No. 18A, 18B, 18C.)</p> <p>8 THE DEPONENT: Okay.</p> <p>9 MR. JONES: Let me guess, you want to do a</p> <p>10 redirect, but we don't have an opportunity to do a</p> <p>11 re-recross.</p> <p>12 MR. ROSENBLATT: No. I actually don't have</p> <p>13 anything.</p> <p>14 MR. JONES: Awesome.</p> <p>15 MR. ROSENBLATT: We're good.</p> <p>16 (Whereupon, the deposition of Joseph M. Carbone,</p> <p>17 M.D., was concluded at 8:58 p.m.)</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p>1 - - - - -</p> <p style="text-align: center;">E R R A T A</p> <p>2 - - - - -</p> <p>3</p> <p>4 PAGE LINE CHANGE</p> <p>5 _____</p> <p>6 REASON: _____</p> <p>7 _____</p> <p>8 REASON: _____</p> <p>9 _____</p> <p>10 REASON: _____</p> <p>11 _____</p> <p>12 REASON: _____</p> <p>13 _____</p> <p>14 REASON: _____</p> <p>15 _____</p> <p>16 REASON: _____</p> <p>17 _____</p> <p>18 REASON: _____</p> <p>19 _____</p> <p>20 REASON: _____</p> <p>21 _____</p> <p>22 REASON: _____</p> <p>23 _____</p> <p>24 REASON: _____</p>
<p style="text-align: center;">Page 159</p> <p>1 COMMONWEALTH OF VIRGINIA AT LARGE, to wit:</p> <p>2 I, Bobbi J. Case, Registered Professional Court</p> <p>3 Reporter and Notary Public for the Commonwealth of</p> <p>4 Virginia at Large, and whose commission expires</p> <p>5 October 31, 2019, do hereby certify that the</p> <p>6 within-named deponent, JOSEPH M. CARBONE, M.D.,</p> <p>7 appeared before me at Danville, Virginia, as</p> <p>8 hereinbefore set forth, and after being first duly</p> <p>9 sworn by me, was thereupon examined by counsel for the</p> <p>10 parties; that his examination was recorded in Stenotype</p> <p>11 by me and reduced to computer printout under my</p> <p>12 direction; and that the foregoing constitutes a true,</p> <p>13 accurate, and complete transcript of such proceeding,</p> <p>14 produced to the best of my abilities. I further</p> <p>15 certify that deponent was not advised of reading and</p> <p>16 signing. I further certify that I am not related to</p> <p>17 nor otherwise associated with any counsel or party to</p> <p>18 this proceeding, nor otherwise interested in the event</p> <p>19 thereof.</p> <p>20 Given under my hand and notary seal this 23rd</p> <p>21 day of March 2016 at Virginia Beach, Virginia.</p> <p>22</p> <p>23 _____</p> <p>24 Bobbi J. Case, RPR, CCR NCRA No. 837774, VCRA No. 0315042 Notary No. 181018</p>	<p>1</p> <p>2 ACKNOWLEDGMENT OF DEPONENT</p> <p>3</p> <p>4 I, _____, do</p> <p>5 hereby certify that I have read the</p> <p>6 foregoing pages, and that the same is</p> <p>7 a correct transcription of the answers</p> <p>8 given by me to the questions therein</p> <p>9 propounded, except for the corrections or</p> <p>10 changes in form or substance, if any,</p> <p>11 noted in the attached Errata Sheet.</p> <p>12</p> <p>13</p> <p>14 _____</p> <p>15 JOSEPH M. CARBONE, M.D. DATE</p> <p>16</p> <p>17</p> <p>18 Subscribed and sworn</p> <p>19 to before me this</p> <p>20 _____ day of _____, 20____.</p> <p>21 My commission expires: _____</p> <p>22</p> <p>23 _____</p> <p>24 Notary Public</p>

41 (Pages 158 to 161)

1 COMMONWEALTH OF VIRGINIA AT LARGE, to wit:

2 I, Bobbi J. Case, Registered Professional Court
3 Reporter and Notary Public for the Commonwealth of
4 Virginia at Large, and whose commission expires
5 October 31, 2019, do hereby certify that the
6 within-named deponent, JOSEPH M. CARBONE, M.D.,
7 appeared before me at Danville, Virginia, as
8 hereinbefore set forth, and after being first duly
9 sworn by me, was thereupon examined by counsel for the
10 parties; that his examination was recorded in Stenotype
11 by me and reduced to computer printout under my
12 direction; and that the foregoing constitutes a true,
13 accurate, and complete transcript of such proceeding,
14 produced to the best of my abilities. I further
15 certify that deponent was not advised of reading and
16 signing. I further certify that I am not related to
17 nor otherwise associated with any counsel or party to
18 this proceeding, nor otherwise interested in the event
19 thereof.

20 Given under my hand and notary seal this 23rd
21 day of March 2016 at Virginia Beach, Virginia.

22 
23 Bobbi J. Case, RPR, CCR
24 NCRA No. 837774, VCRA No. 0315042
Notary No. 181018